Patterson Belknap Webb & Tyler LLP

1133 Avenue of the Americas New York, NY 10036-6710 212.336.2000 fax 212.336.2222 www.pbwt.com

February 20, 2019

Erik Haas
Partner
(212) 336-2117
ehaas@pbwt.com

By ECF

The Honorable Freda L. Wolfson, U.S.D.J.
United States District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: *Hirschfeld v. Beckerle*, et al., No. 18-cv-14796 (FLW) (DEA)

Dear Judge Wolfson:

We, along with Riker, Danzig, Scherer, Hyland & Perretti LLP, represent the individual defendants (the "Directors") in this matter. We respectfully submit this letter to join in the motion to dismiss the Complaint (Dkt. No. 1) submitted by nominal defendant Johnson & Johnson ("J&J"). As set forth in J&J's motion, Plaintiff's single, derivative claim is barred as a matter of law and the Complaint should be dismissed with prejudice and without leave to amend.

First, Plaintiff failed to make a demand on J&J's Board of Directors prior to commencing suit, which is a mandatory condition precedent to bringing a derivative action. *See* N.J.S.A. § 14A:3-6.3 (2018). That alone warrants dismissal of the Complaint without leave to amend. *See, e.g.*, *Ark. Teacher Ret. Sys. v. Alsop*, 2007 U.S. Dist. LEXIS 99152 (D. Mass. Aug. 29, 2007) (denying leave to replead under analogous statute).

Second, dismissal without leave to amend is particularly appropriate because Plaintiff's own allegations and the public record he incorporates by reference demonstrate he has no viable claim. Plaintiff alleges that a majority of Directors knowingly disregarded "red flags" that J&J's talc-based products cause cancer and thus would face a substantial likelihood of liability if they complied with a demand. *See*, *e.g.*, Compl. ¶¶ 101-03. To maintain this claim, Plaintiff must plead with particularity and prove "a sustained or systemic failure of the board to exercise oversight" reflecting a "conscious disregard for their duties." *In re Johnson & Johnson Derivative Litig.* ("*J&J*"), 865 F. Supp. 2d 545, 558-59 (D.N.J. 2011).[1] As Plaintiff admits, however, J&J management adamantly disputes that J&J's talc-based products cause cancer, a position based upon extensive scientific analysis. Compl. ¶ 99. Plaintiff further tacitly concedes that the U.S. Food and Drug Administration ("FDA") has allowed the continued sale of J&J's talc-based products, without any warning about the purported risk of cancer. *Id.* at ¶¶ 60, 79.

[1] This Court has acknowledged that this "failure of oversight" claim is "possibly the most difficult theory in corporation law" to maintain. *J&J*, 865 F. Supp. 2d at 557 (quoting *In re Caremark Int'l Inc. Derivative Litig.*, 698 A.2d 959, 967 (Del. Ch. 1996)). Moreover, it is not enough to allege a breach of the duty of care; the Directors may be held liable only for breach of the duty of loyalty or bad faith, knowing violation of the law, or receipt of an improper personal benefit. N.J.S.A. § 14A:2-7(3).

The FDA did so with express rejection of the discredited scientific studies upon which Plaintiff relies. *See* J&J Br. at 19-23. Likewise, although Plaintiff references an adverse jury verdict against J&J (Compl. ¶¶ 82-89), he disregards the contrary decisions rejecting as baseless and biased the science on which he relies, *see, e.g.*, *Coordinated v. Johnson & Johnson*, 2017 Cal. Super. LEXIS 8757 (Nov. 17, 2017) (setting aside plaintiff's verdict because expert offered no basis to conclude "talc is a scientifically plausible cause of ovarian cancer"); *Carl v. Johnson & Johnson*, 2016 N.J. Super. Unpub. LEXIS 2102 (Sept. 2, 2016) (granting motion to strike plaintiff's expert testimony as unreliable basis to find that talc-based products caused cancer, and granting summary judgment to J&J). Thus, not only has Plaintiff failed to plead that the Directors received the purported "red flags" that are the predicate of his claim (J&J Br. at 19-23), his concessions and the public record establish that he cannot plead or prove that (i) those red flags refuted J&J management's reasoned conclusion that its talc-based products do not cause cancer, or (ii) a majority of the Directors willfully disregarded those red flags such that they face liability for not requiring management to take a different course. The allegations and public record show nothing more than that the Directors have a good-faith basis to support management's decision to fight the underlying claims. It therefore would be futile to replead.

Third, the futility of any amendment is underscored by Plaintiff's failure to tailor his allegations to the individual Directors, as he is required to do. *See, e.g.*, *J&J*, 865 F. Supp. 2d at 575.[2] Instead, Plaintiff summarily asserts that, by virtue of their membership on two Board committees—the Science, Technology & Sustainability ("STS") Committee and Regulatory, Compliance & Government Affairs ("RCGA") Committee—a majority of the Directors were aware of and disregarded health risks to millions of consumers. Compl. ¶ 74. Plaintiff's allegations are facially deficient and implausible in view of the composition of those committees.

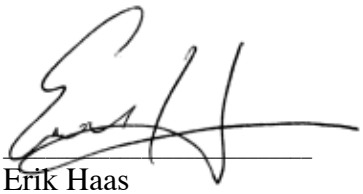
The Director defendants on the STS Committee have well-documented careers dedicated to the preservation of human life. The Chair of the Committee, Dr. Beckerle, is CEO and Director of the Huntsman Cancer Institute and previously served on the Board of Directors of the American Association for Cancer Research. *Id.* ¶ 16. Dr. Doudna is Professor of Biochemistry and Molecular Biology at the University of California, Berkeley. *Id.* ¶ 19. Dr. McClellan is the former Commissioner of the FDA and Administrator of the Centers for Medicare & Medicaid Services. *Id.* ¶ 21. Dr. Washington is Chancellor for Health Affairs at Duke University and President and CEO of Duke's Health System. *Id.* ¶ 25. The notion that these physicians and public servants would consciously disregard serious risks to public health is specious.

With respect to the RCGA Committee, the Chair, Mr. Prince, is the former Chairman of the Board and CEO of Citigroup Inc. *Id.* ¶ 24. Mr. Davis was Chairman and Worldwide Managing Director of McKinsey & Company. *Id.* ¶ 18. The other members are Drs. Beckerle and McClellan. Plaintiff's accusation that these Directors turned a blind eye to valid evidence that J&J's talc-based products cause cancer is preposterous. The far more plausible inference—consistent with the FDA's position and the overwhelming scientific evidence—is that the Board has acted in good faith to preserve the interests of the public and, in doing so, the Company.

[2] The only exception is one passing allegation against one Director. Compl. ¶ 105.

Plaintiff's claim is baseless and should be dismissed without leave to replead.

Respectfully submitted,



Erik Haas

Riker, Danzig, Scherer, Hyland
& Perretti LLP

By: s/ Edwin F. Chociey, Jr.
Edwin F. Chociey, Jr.

cc: All counsel of record (via ECF)

EXHIBIT A

Ark. Teacher Ret. Sys. v. Alsop

United States District Court for the District of Massachusetts

August 29, 2007, Decided

CIVIL ACTION NO. 06-11459-RCL

Reporter
2007 U.S. Dist. LEXIS 99152 *; 2007 WL 7069609

ARKANSAS TEACHER RETIREMENT SYSTEM, DERIVATIVELY ON BEHALF OF PROGRESS SOFTWARE CORPORATION, Plaintiff, v. JOSEPH W. ALSOP, DAVID IRELAND, RICHARD D. REIDY, NORMAN R. ROBERTSON, PETER SLIWKOWSKI, DAVID P. VESTY, DAVID H. BENTON, ROGER J. HEINEN, MICHAEL L. MARK, SCOTT A. McGREGOR, AMRAM RASIEL and LARRY R. HARRIS, Defendants, And PROGRESS SOFTWARE CORPORATION, Nominal Defendant.

LexisNexis® Headnotes

Civil Procedure > ... > Defenses, Demurrers & Objections > Motions to Dismiss > Failure to State Claim

Civil Procedure > ... > Pleadings > Complaints > General Overview

HN1[] **Motions to Dismiss, Failure to State Claim**

The standard of review for a motion to dismiss under *Fed. R. Civ. P. 12(b)(6)* is well established. A court accepts the factual allegations in the complaint as true and draws all reasonable inferences in favor of the plaintiff. Construing such inferences in the plaintiff's favor, dismissal is appropriate only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations. Ordinarily, a court is constrained by the four corners of the complaint. A narrow exception nonetheless exists for documents the authenticity of which are not disputed by the parties; for official public records; for documents central to the plaintiff's claim; or for documents sufficiently referred to in the complaint.

Business & Corporate Law > ... > Directors & Officers > Compensation > Salaries

HN2[] **Compensation, Salaries**

A stock option gives the owner the right to purchase a set number of shares at a specific price for a set period of time.

Business & Corporate Law > ... > Actions Against Corporations > Standing > Claim Presentation

HN3[] **Standing, Claim Presentation**

The Massachusetts Business Corporations Act, *Mass. Gen. Laws ch. 156D, § 1.01 et seq.*, allows a corporation 90 days from the date of a shareholder's demand to take suitable action to consider whether to reject the demand. *Mass. Gen. Laws ch. 156D, § 7.42(2)*.

Business & Corporate Law > ... > Actions Against Corporations > Standing > Claim Presentation

HN4 **Standing, Claim Presentation**

The Massachusetts Business Corporations Act, Mass. Gen. Laws ch. 156D, § 1.01 et seq., allows a shareholder to shorten the 90 day period a corporation is granted to consider whether to reject a shareholder's demand to take suitable action if "irreparable injury" would result. Mass. Gen. Laws ch. 156D, § 7.42(2).

Business & Corporate Law > ... > Actions Against Corporations > Standing > Claim Presentation

Civil Procedure > ... > Class Actions > Derivative Actions > Demand Futility

Business & Corporate Law > ... > Standing > Demands > Futility

Civil Procedure > ... > Class Actions > Derivative Actions > Demand Requirement

HN5 **Standing, Claim Presentation**

Both Fed. R. Civ. P. 23.1 and Mass. Gen. Laws ch. 156D, § 7.42 contain requirements that a shareholder make a demand on a corporation's board of directors before filing a derivative suit. Fed. R. Civ. P. 23.1 governs the pleading requirements of a shareholder derivative action in federal court. State law, in turn, governs the substantive requirements of the demand. In considering the contours of a demand and whether to excuse a demand on the basis of futility, a federal court must look to the law of the state of incorporation of the entity sued.

Business & Corporate Law > ... > Actions Against Corporations > Standing > Claim Presentation

HN6 **Standing, Claim Presentation**

With respect to federal claims under *15 U.S.C.S. § 78j(b)* and 17 C.F.R. § 240.10b-5, application of the demand requirements of Mass. Gen. Laws ch. 156D, § 7.42 is not inconsistent with the policies underlying the federal statute.

Business & Corporate Law > ... > Actions Against Corporations > Standing > Claim Presentation

Civil Procedure > ... > Class Actions > Derivative Actions > Demand Requirement

HN7 **Standing, Claim Presentation**

Mass. Gen. Laws ch. 156D, § 7.42 imposes a substantive demand requirement on shareholders seeking to bring derivative suits on behalf of a corporation.

Governments > Legislation > Interpretation

HN8 **Legislation, Interpretation**

In all statutory construction cases, the starting point is the language of the statute. If the language of a statute or regulation has a plain and ordinary meaning, courts need look no further and should apply the statute or regulation as it is written. Courts should look beyond the words of the statute to its history, policy or other extrinsic aids to ascertain statutory intent only when the language is ambiguous.

Business & Corporate Law > ... > Actions Against Corporations > Standing > Claim Presentation

Civil Procedure > ... > Class Actions > Derivative Actions > Demand Requirement

HN9 **Standing, Claim Presentation**

See Mass. Gen. Laws ch. 156D, § 7.42.

Business & Corporate Law > ... > Actions Against Corporations > Standing > Claim Presentation

Civil Procedure > ... > Class Actions > Derivative Actions > Demand Requirement

Civil Procedure > ... > Pleadings > Amendment of Pleadings > General Overview

Civil Procedure > ... > Pleadings > Complaints > General Overview

HN10 **Standing, Claim Presentation**

The plain and ordinary meaning of Mass. Gen. Laws ch. 156D, § 7.42 requires a shareholder to make a written demand before he commences a derivative proceeding. The ordinary meaning of the term "commence" is to begin or start. The statute defines "derivative proceeding" as a civil suit in the right of a domestic corporation. Mass. Gen. Laws ch. 156D, § 7.40. Commencing a civil suit is commonly understood as filing a complaint in court or mailing the complaint with the filing fee to the clerk. Mass. R. Civ. P. 3; Fed. R. Civ. P. 3. Filing an amended complaint does not "commence" a civil suit. Rather, it is part of a continuation of an ongoing, existing suit.

Business & Corporate Law > ... > Actions Against Corporations > Standing > Claim Presentation

Civil Procedure > ... > Class Actions > Derivative Actions > Demand Requirement

HN11 **Standing, Claim Presentation**

The drafters of Mass. Gen. Laws ch. 156D, § 7.42, requiring a shareholder to make a demand on a corporation before filing a derivative suit, chose to separate the two independent clauses in Mass. Gen. Laws ch. 156D, § 7.42(1) and (2) with separate numerical parentheses, a semicolon and a conjunctive link. The drafters thereby intended to establish two separate requirements for a shareholder to satisfy before he could commence a derivative proceeding. It is only the second subsection that contains "irreparable injury" language allowing a shareholder to file suit before the expiration of 90 days after making a demand on a corporation. Mass. Gen. Laws ch. 156D, § 7.42, Comment, clarifies that a finding of "irreparable injury" equates to the entry of a preliminary injunction and may include consideration of factors such as the possible expiration of the statute of limitations.

Business & Corporate Law > ... > Management Duties & Liabilities > Fiduciary Duties > Business Judgment Rule

Civil Procedure > ... > Class Actions > Derivative Actions > Demand Futility

Business & Corporate Law > ... > Standing > Demands > Futility

HN12 **Fiduciary Duties, Business Judgment Rule**

The plain language of Mass. Gen. Laws ch. 156D, § 7.42, requiring a shareholder to make a demand on a corporation before filing a derivative suit, does not contain a futility exception. The statute eliminates futility as an exception to making a pre-suit demand upon the corporation. The drafters did not include an examination of the interest,

disinterest or independence of the board of directors as a factor to consider when examining whether a written demand has been made upon the corporation. *Mass. Gen. Laws ch. 156D, § 7.42(1)*. Instead, the drafters placed this inquiry in *Mass. Gen. Laws ch. 156D, § 7.44* in the context of whether to apply the business judgment rule's evidentiary presumption.

Business & Corporate Law > Corporations > General Overview

Governments > Legislation > Interpretation

Governments > Courts > Judicial Precedent

HN13 **Business & Corporate Law, Corporations**

Cases outside Massachusetts interpreting statutory provisions substantially equivalent to provisions in the American Bar Association's Model Business Corporation Act provide guidance in interpreting the Massachusetts Business Corporation Act, *Mass. Gen. Laws ch. 156D, § 1.01 et seq.*, in the absence of controlling Massachusetts precedent.

Business & Corporate Law > ... > Actions Against Corporations > Standing > Claim Presentation

Civil Procedure > ... > Class Actions > Derivative Actions > Demand Requirement

Governments > Legislation > Interpretation

HN14 **Standing, Claim Presentation**

The plain language of *Mass. Gen. Laws ch. 156D, § 7.42(1)* provides that a plaintiff cannot commence a derivative action until a written demand has been made on a corporation. It is one thing to impose a gloss on a statute that achieves formal compliance with the statute to rescue a transaction where no prejudice occurred. It is another to make lack of prejudice itself a substitute for formal compliance.

Business & Corporate Law > ... > Actions Against Corporations > Standing > Claim Presentation

Civil Procedure > ... > Class Actions > Derivative Actions > Demand Requirement

HN15 **Standing, Claim Presentation**

Mass. Gen. Laws ch. 156D, § 7.42, Comment, unequivocally states that there is no obligation on the part of a corporation to respond to a shareholder's pre-suit demand to take appropriate action.

Business & Corporate Law > ... > Actions Against Corporations > Standing > Claim Presentation

Civil Procedure > ... > Class Actions > Derivative Actions > Demand Requirement

HN16 **Standing, Claim Presentation**

Although not necessary in light of the plain language of *Mass. Gen. Laws ch. 156D, § 7.42*, the policy of the statute confirms the conclusion that it requires a shareholder to make a pre-suit demand on a corporation before filing a derivative suit. A demand allows the corporation to protect the authority of the board of directors to decide whether to pursue a lawsuit on behalf of the corporation. The statute's drafters concur that the demand rule is intended to give the derivative corporation itself the opportunity to take over a suit which was brought on its behalf in the first place, and thus to allow the directors the chance to occupy their normal status as conductors of the corporation's affairs. *Mass. Gen. Laws ch. 156D, §*

7.42, Comment. Requiring the shareholder to make a written demand upon the corporation before filing suit gives initial deference to the corporate body to manage the corporation's internal affairs. It also creates a simple rule thereby avoiding litigation regarding whether to excuse demand.

Counsel: **[*1]** For Arkansas Teacher Retirement System, Derivatively on Behalf of Progress Software Corporation, Plaintiff: Adam H. Wierzbowski, Salvatore J. Graziano, LEAD ATTORNEYS, Bernstein Litowitz Berger & Grossmann LLP, New York, NY; Glen DeValerio, LEAD ATTORNEY, Patrick F. Welch, Berman DeValerio, Boston, MA; Jeffrey C Block, LEAD ATTORNEY, Berman DeValerio Pease Tabacco Burt & Pucillo, Boston, MA.

For Joseph W Alsop, Defendant: Joseph F. Savage, Jr., LEAD ATTORNEY, Inez H. Friedman-Boyce, Monica Meier Franceschini, Goodwin Procter LLP, Boston, MA.

For David Ireland, Richard D Reidy, Peter Sliwkowski, David P Vesty, Michael L Mark, Scott A McGregor, Amram Rasiel, Larry R Harris, Defendants: Alan D. Rose, Jr., Alan D. Rose, Sr., LEAD ATTORNEYS, Rose, Chinitz & Rose, Boston, MA; Meredith Ann Wilson, LEAD ATTORNEY, Rose, Chinitz & Rose, Boston, MA.

For Norman R Robertson, Defendant: Alan D. Rose, Jr., Alan D. Rose, Sr., LEAD ATTORNEYS, Rose, Chinitz & Rose, Boston, MA; Brien T. O'Connor, LEAD ATTORNEY, Ropes & Gray, Boston, MA; Meredith Ann Wilson, LEAD ATTORNEY, Rose, Chinitz & Rose, Boston, MA; Timothy James Casey, LEAD ATTORNEY, Office of the Attorney General (MA), Boston, MA.

For David H Benton, **[*2]** Defendant: Alan D. Rose, Jr., Alan D. Rose, Sr., LEAD ATTORNEYS, Rose, Chinitz & Rose, Boston, MA; Meredith Ann Wilson, LEAD ATTORNEY, Rose, Chinitz & Rose, Boston, MA; R.J. Cinquegrana, LEAD ATTORNEY, Dara Z. Kesselheim, Joseph H. Zwicker, Choate, Hall & Stewart, Boston, MA; John R. Baraniak, Jr., Choate, Hall & Stewart LLP*, Boston, MA.

For Roger J Heinen, Defendant: Brian E. Pastuszenski, Goodwin Procter LLP, Boston, MA; Stuart M. Glass, Goodwin Procter, LLP, Boston, MA.

For Progress Software Corporation, Defendant: Brandon F. White, LEAD ATTORNEY, Foley Hoag LLP, Boston, MA; Matthew C. Baltay, LEAD ATTORNEY, Foley Hoag LLP, Boston, MA; Patrick J. Vallely, LEAD ATTORNEY, Foley Hoag LLP, Boston, MA.

For Special Litigation Committee to Progress Software Corporation, Interested Party: Paula-Marie Uscilla, Peter J. Simshauser, Thomas J. Dougherty, LEAD ATTORNEYS, Skadden, Arps, Slate, Meagher & Flom LLP, Boston, MA.

Judges: MARIANNE B. BOWLER, United States Magistrate Judge.

Opinion by: MARIANNE B. BOWLER

Opinion

REPORT AND RECOMMENDATION RE: DEFENDANTS' MOTION TO DISMISS AMENDED VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT (DOCKET ENTRY # 46); MOTION OF DEFENDANT DAVID H. BENTON TO DISMISS COUNTS I-II OF PLAINTIFF'S AMENDED [*3] COMPLAINT (DOCKET ENTRY # 49); DEFENDANT JOSEPH W. ALSOP'S MOTION TO DISMISS AMENDED VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT (DOCKET ENTRY # 51); MOTION TO DISMISS NORMAN R. ROBERTSON (DOCKET ENTRY # 56); DEFENDANT ROGER J. HEINEN'S MOTION TO DISMISS AMENDED VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT (DOCKET ENTRY # 57); INDIVIDUAL DEFENDANTS DAVID

IRELAND, RICHARD D. REIDY, PETER SLIWKOWSKI AND DAVID P. VESTY'S JOINT MOTION TO DISMISS THE AMENDED VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT (DOCKET ENTRY # 75); INDIVIDUAL DEFENDANTS MICHAEL L. MARK, SCOTT A. MCGREGOR, AMRAM RASIEL AND LARRY R. HARRIS'S JOINT MOTION TO DISMISS AMENDED VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT (DOCKET ENTRY # 77)

BOWLER, U.S.M.J.

Plaintiff Arkansas Teacher Retirement System ("plaintiff") filed this shareholder derivative action on behalf of nominal defendant Progress Software Corporation ("PSC" or "the company") against certain current and former officers and/or directors due to their receipt of back dated company stock options. PSC presently moves to dismiss the amended complaint on the basis that plaintiff did not make a pre-suit demand to the company before instituting suit as required under *section 7.42 of Massachusetts General Laws chapter 156D*, **[*4]** commonly known as the Massachusetts Business Corporations Act ("MBCA"). (Docket Entry # 46). In separate motions to dismiss (Docket Entry # # 49, 51, 56, 57, 75 & 77), each defendant joined in and/or adopted PSC's argument. [1]

On May 14, 2007, this court heard oral argument on the pre-suit demand issue. One day later, this court allowed the motion to address only the pre-suit demand issue (Docket Entry # 84) before proceeding to the other issues raised in the motions to dismiss. Having received supplemental memoranda from plaintiff and PSC, the matter is ripe for review.

[1] Benton's motion, which is captioned as a motion to dismiss only counts I and II, moves for a dismissal of the amended complaint "as against him in its entirety." (Docket Entry # 49, p. 2; Docket Entry # 50, p. 12).

STANDARD OF REVIEW

HN1[↑] The standard of review for a motion to dismiss under *Rule 12(b)(6), Fed. R. Civ. P.* ("*Rule 12(b)(6)*"), is well established. This court accepts the factual allegations in the amended complaint as true and draws all reasonable inferences in favor of plaintiff. See *Alternative Energy v. St. Paul Fire & Marine, 267 F.3d 30, 33 (1st Cir. 2001)* (on a **[*5]** motion to dismiss, court accepts all allegations in complaint as true and construes "all reasonable inferences in favor of the plaintiffs"). Construing such inferences in plaintiff's favor, dismissal is appropriate "'only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations.'" *Swierkiewicz v. Sorema N.A., 534 U.S. 506, 514, 122 S. Ct. 992, 152 L. Ed. 2d 1 (2002)*; accord *Blackstone Realty LLC v. FDIC, 244 F.3d 193, 197 (1st Cir. 2001)* (dismissal is proper "only if, under the facts alleged," the plaintiff "cannot recover on any viable theory"); *State Street Bank and Trust Company v. Denman Tire Corporation, 240 F.3d 83, 87 (1st Cir. 2001)* (dismissal appropriate "only if it 'appears to a certainty that the plaintiff would be unable to recover under any set of facts'").

Ordinarily, a court "is constrained by the four corners of the complaint." *Stegall v. Ladner, 394 F.Supp.2d 358, 360 (D.Mass. 2005)*. A narrow exception nonetheless exists for "'documents the authenticity of which are not disputed by the parties; for official public records; for documents central to [the] plaintiffs' claim; or for documents sufficiently referred to in the complaint.'" *Alternative Energy, Inc. v. St. Paul Fire and Marine Insurance Co., 267 F.3d at 33*. **[*6]** Inasmuch as the parties do not challenge the authenticity of the August 28, 2006 demand letter as well as certain Securities and Exchange Commission ("SEC") official public documents, this court may consider them without converting the *Rule 12(b)(6)* motion into a summary judgment motion.

BACKGROUND

PSC is a Massachusetts corporation with a principal place of business in Bedford, Massachusetts. It is a global provider of products and services concerning the development, deployment and management of business software applications.

Defendant Joseph W. Alsop ("Alsop") co-founded the company in 1981 and has been a director since that time. In 2000, he became the company's Chief Executive Officer after serving as President. Together with defendants Norman R. Robertson ("Robertson"), Vice President of Finance and Chief Financial Officer, David P. Vesty ("Vesty"), Vice President of Worldwide Sales from 1996 to 1999, and David H. Benton ("Benton"), Vice President and Corporate Controller, Alsop received a back dated stock option purportedly on March 3, 1997, at the exercise price of $ 14.13. *HN2*[↑] A stock option gives the owner the right to purchase a set number of shares at a specific price for a set **[*7]** period of time. Based on the public trading price of company stock, plaintiff calculates the $ 14.13 price on March 3, 1997, as the lowest stock price of the month and of the fiscal quarter. [2]

Additional back dated stock options awarded to various defendants at unusually favorable and statistically improbable dates took place on December 22, 1997; February 3, 1998; September 1, 1998; February 10, 1999; May 17, 1999; February 18, 2000; October 6, 2000; April 3, 2001; October 10, 2001; and August 2, 2002. Addressing the options chronologically, Robertson received a back dated stock option purportedly on December 22, 1997, at the exercise price of $ 13.08. The $ 13.08 price was the lowest stock price for the next 20 days during which time the price increased to $ 22.88.

Defendant David Ireland ("Ireland"), President of the company's OpenEdge Division, received a back dated **[*8]** stock option purportedly on February 3, 1998, at the exercise price of $ 14.42. The stock price on February 3 was the lowest trading price for the 20 days immediately before and after that date. Other defendants receiving back dated stock options purportedly on February 3 include: Alsop; defendant Richard D. Reidy ("Reidy"), President of the company's DataDirect Technologies operating unit; Robertson; Vesty; and defendant Scott A. McGregor ("McGregor"), a member of the board of directors since 1998.

Alsop and Ireland received back dated stock options purportedly on September 1, 1998, at the exercise price of $ 18.00. The $ 18.00 stock price on September 1 was the lowest price PSC stock traded for during the entire fiscal year.

Alsop, Ireland, Reidy, Robertson, Vesty and Benton received back dated stock options purportedly on February 10, 1999, at the exercise price of $ 12.81. The price was the lowest PSC stock traded for during the fiscal quarter.

Alsop, Ireland, Reidy, Robertson, Vesty and Benton received back dated stock options purportedly on May 17, 1999, at the exercise price of $ 10.47. Like the exercise price of the September 1, 1998 stock option, the $ 10.47 exercise price was **[*9]** the lowest trading price for the entire fiscal year. Alsop, Ireland, Reidy, Robertson and defendants Larry R. Harris ("Harris"), Heinen, Michael L. Mark ("Mark") and Amram Rasiel ("Rasiel"), all directors at the company during the relevant time period, received back dated stock options purportedly on April 3, 2001, at the exercise price of $ 12.81. Again, the $ 12.81 price was the lowest trading price for company stock during that entire fiscal year.

As previously stated, additional back dating took place on February 18, 2000; October 6, 2000; October 10, 2001; and August 2, 2002. Alsop, Ireland, Reidy, Robertson, Benton, Heinen, McGregor, Mark, Rasiel and Harris each received back dated options on one or more of these

[2] The joint memorandum filed by Alsop, Robertson, Benton and defendant Roger J. Heinen ("Heinen") points out that the public stock prices used by plaintiff to calculate the price range with respect to the March 3, 1997 stock option were available no later than April 1997 thereby triggering a five year limitations period.

purported dates. In addition, defendant Peter Sliwkowski ("Sliwkowski"), President of one of the company's principal operating units, received approximately 50,000 back dated stock options during the relevant time period. All of these defendants received the foregoing stock options at statistically unlikely low price points resulting in the realization of millions of dollars of unjustified compensation. By exercising these options during the 1998 to 2005 fiscal years, **[*10]** Alsop realized approximately $ 22,000,000, Ireland realized approximately $ 9,900,000, Reidy realized approximately $ 9,500,000, Robertson realized approximately $ 7,500,000 and Vesty realized approximately $ 4,500,000.

The back dating did not comply with company stock option plans approved by shareholders on August 19, 1994 ("the 1994 plan") and April 25, 1997 ("the 1997 plan"). [3] Under these plans, a company compensation committee ("the compensation committee") determined the exercise prices of stock options. Both the 1994 and 1997 plans required the compensation committee to set the exercise price "on the date of the grant" and prohibited the committee from establishing a price lower than the publicly traded closing price on that date. Compensation committee members, who also set the level of executive compensation, decided both the terms of the stock options and the exercise prices. Heinen served as a member of the compensation committee from 2003 to the present and McGregor was a member from 1999 to the present. The board of directors repeatedly approved the back dated stock options.

The back dating inevitably led to inaccurate reporting of financial data. The difference between the exercise price and the actual market price on the purported date of the stock option constituted unreported executive compensation. PSC did not report the difference as an expense thereby contravening a provision of generally accepted accounting principles or GAAP. The company, with the approval of each individual defendant, [4] thus disseminated false financial statements including various Form 10-K filings from 1997 to 2005. Again with the approval of the individual defendants, the company annually filed false proxy statements on SEC Form 14A from 1998 to 2003.

PSC's audit committee oversaw the preparation of financial statements and the adequacy of internal controls for financial reporting. The committee's oversight extended to the company's quarterly and annual financial statements. Because the financial statements did not account for the true amount of compensation awarded through the back dated stock options, **[*12]** however, the statements proved false.

On June 19, 2006, PSC announced that the audit committee was undertaking a review of the company's stock option practices beginning with the 1996 fiscal year. Assisted by outside counsel, the audit committee included Heinen, Mark and Rasiel, all of whom had received back dated options in the past. [5] The June announcement warned that the review could result in a restatement of past financial statements to increase the amount of charges associated with past stock options. Eight days later the company disclosed that the SEC's Boston office was conducting an informal inquiry into the company's stock option practices for the fiscal years 1996 to 2002. PSC then delayed filing quarterly SEC Form 10-Qs for the periods ending May 31, 2006 and August 31, 2006, resulting in notices from NASDAQ [6] about the possible

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[3] Heinen, Mark, McGregor, Rasiel and Harris ("the director defendants"), as PSC directors, received **[*11]** stock options under an additional plan.

[4] The individual defendants consist of Alsop, Ireland, Reidy, Robertson, Sliwkowski, Vesty, Benton, Heinen, Mark, McGregor, Rasiel and Harris.

[5] Heinen and Mark were members of the audit committee respectively from 2000 and 1999 to the present. Rasiel was a member of the committee during the relevant time period.

[6] "'NASDAQ' stands for the National Association of Securities Dealers Automated Quotation," which is "'the **[*13]** largest electronic, screen-based market in the world.'" *In re PolyMedica Corp. Securities Litigation, 432 F.3d 1, 3 (1st Cir. 2005)*.

delisting of PSC stock.

On August 17, 2006, plaintiff filed the original complaint. The original complaint recites facts similar to those in the amended complaint against the same parties. Both the original and amended complaints also allege violations of section 10(b) of the Securities Exchange Act of 1934, *15 U.S.C. § 78j(b)* ("section 10(b)"), and *Rule 10b-5* promulgated thereunder, *17 C.F.R. § 240.10b-5* ("*Rule 10b-5*"), against the individual defendants (Count I). Count II alleges that the individual defendants breached fiduciary duties resulting in substantial harm to PSC. Alsop, Heinen, Mark, McGregor, Rasiel and Harris, all members of the board of directors at various times, allegedly aided and abetted the violations of fiduciary duties (Count III). Counts IV and V seek recovery for unjust enrichment and rescission of the stock option contracts against the individual defendants.

The original complaint particularizes the reasons for excusing plaintiff from making a pre-suit demand. According to the complaint, a demand would be futile because back dating stock options was outside **[*14]** the scope of the board of directors' authority, served no legitimate purpose and was not protected by the business judgment rule. Alsop, Heinen, Mark, McGregor and Rasiel presently sit on the board of directors. Because they personally benefitted from the back dating, they cannot objectively evaluate the problem, according to the original complaint. The complaint additionally points out that four of these five board members sat on the compensation and/or the audit committee thereby precluding any disinterest or independence on their part. In 11 additional paragraphs, the original complaint describes the conflicts and lack of impartiality of Alsop, Heinen, Mark, McGregor and Rasiel.

On August 28, 2006, after the filing of the original complaint, plaintiff sent a demand letter to the board of directors. [7] The letter demanded that the board take immediate action to remedy the back dating. It included a proposed stipulation to stay any response to the original complaint for a 90 day time period. [8]

The demand letter asserts that preserving the status quo and not taking immediate remedial action would likely "cause irreparable harm." [9] Examples of irreparable harm posited in the letter include that grantees would exercise additional stock options thereby depleting company funds, damaging the integrity of the stock, diluting the value and voting rights of existing shares and increasing the grantees' control of the company. (Docket Entry # 62, Ex. C).

On August 29, 2006, PSC released a statement acknowledging that the audit committee "concluded that the actual measurement dates for determining the accounting treatment of stock option grants differ from the measurement dates used by the Company in preparing its financial statements." (Docket Entry # 26, P 58). The statement also recognized the widespread nature of the stock option problem as extending beyond options to executive officers. According to the statement, PSC would not be able to announce financial results for **[*16]** the third quarter or file a quarterly report until it had determined the correct expense amount for stock option compensation. According to the company, it expected to record additional stock based compensation charges in the range of $ 20,000,000 to $ 30,000,000 for the December 1995 to February 2006 time period. Viewing the record in plaintiff's favor, the statements confirm the existence of back dating.

On September 9, 2006, PSC and the individual

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[7] The demand preceded any appearance in the case on behalf of a defendant.

[8] The 90 day period corresponds with a statutory period in *HN3*[↑] the MBCA which allows a corporation 90 days from the date of **[*15]** demand to consider whether to reject a demand. *Mass. Gen. L. ch. 156D, § 7.42 (2)*.

[9] *HN4*[↑] The MBCA allows a shareholder to shorten the 90 day period if "irreparable injury" would result. *Mass. Gen. L. ch. 156D, § 7.42(2)*.

defendants filed a motion to dismiss the original complaint because of the absence of a pre-suit demand. [10] Plaintiff filed an opposition and, more notably, on November 30, 2007, filed the amended complaint alleging that plaintiff had made a demand and waited the allotted 90 days before filing the amended complaint. A few days later, the district judge set a hearing on the motion to dismiss. On December 8, 2006, however, plaintiff filed a motion to deny the motion to dismiss on the basis that filing the amended complaint mooted the motion to dismiss. The district judge agreed and the motion to dismiss the original complaint was terminated on January 4, 2007.

Meanwhile, on September 19, 2006, PSC disclosed the creation of a special committee of the board of directors to continue the audit committee's review of stock option practices. The board of directors, consisting at the time of Alsop, Heinen, Mark, McGregor and Rasiel, all of whom had received back dated stock options, appointed the special committee's members. PSC's outside counsel continued to assist with the review.

On November 9, 2006, the board of directors named a new director, Charles Kane ("Kane"), and appointed him to the special committee. Although not an executive at the company, Kane has held senior positions at Deloitte & Touche, LLP, PSC's auditor since 1997, and served as the chief financial officer of two different PSC clients.

On January 23, 2007, PSC filed the present motion to dismiss the amended complaint due to the absence of a pre-suit demand. On March 7, 2007, the board of directors allegedly appointed a special litigation committee ("SLC") consisting of Kane and another newly appointed board member, Barry Bycoff ("Bycoff"). [11] Bycoff was the Chief Executive Officer of Software Development Corporation ("SDC") before selling the company **[*18]** and using the proceeds in 1996 to create Netegrity, a leading developer of enterprise security software. Mark, a PSC director, sat on the boards of SDC and Netegrity with Bycoff, President and Chief Executive Officer of Netegrity. Rasiel, another PSC director, as well as four other individuals, "may be deemed to beneficially own" a total of slightly less than half a million shares of Netegrity common stock. (Docket Entry # 86, Ex. AA, pp. 11-12).

In 2007, two individuals instituted separate lawsuits in Massachusetts Superior Court derivatively on behalf of PSC against the individual defendants, a number of other defendants and PSC as a nominal defendant ("the state court cases"). In April 2007, in light of the formation of the SLC, the parties in the state court cases agreed to stay both actions for 90 days to allow the SLC to conduct an investigation. In late April 2007, the state court cases were stayed.

At the May 14, 2007 hearing, PSC submitted a tolling agreement between the individual defendants, PSC and the SLC agreeing to toll **[*19]** the running of the statute of limitations in this action from August 17, 2006 to August 31, 2007. Executed presumably sometime in "April __, 2007," the agreement was not in effect on August 17, 2006, when plaintiff filed suit. [12] (Docket Entry # 94, Ex. 1).

DISCUSSION

The parties do not dispute that *section 7.42* of the MBCA applies to this derivative suit. PSC is a Massachusetts corporation organized under Massachusetts law. It is therefore subject to the provisions of the act including *section 7.42*. Mass. Gen. L. ch. 156D, Comment to Introduction (MBCA "governs all Massachusetts business corporations").

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[10] Contrary to plaintiff's assertion, defendants engaged in a Local Rule 7.1 conference. **[*17]** (Docket Entry # 22, Ex. 1).

[11] Although this allegation is not included in the amended complaint, the parties concur that PSC formed the special litigation committee on March 7, 2007.

[12] Consideration of the tolling agreement would not alter this court's recommendation of dismissal.

There is also no dispute that this is a derivative shareholder action in which plaintiff sues on behalf of the company. The amended complaint captions itself as a "SHAREHOLDER DERIVATIVE COMPLAINT" (Docket Entry # 26) and the first numbered paragraph reiterates that, "This is a shareholder's derivative action brought in the name and for the benefit of nominal defendant Progress against certain current and former directors." (Docket Entry # 26, P 1).

Plaintiff maintains that it complied with **[*20]** *section 7.42* by making the demand, waiting 90 days and then filing the amended complaint which, as plaintiff correctly points out, supersedes the original complaint. See *Kolling v. American Power Conversion Corporation, 347 F.3d 11, 16 (1st Cir. 2003)* ("amended complaint completely supersedes [Kolling's] original complaint, and thus the original complaint no longer performs any function"). The need to avoid expiration of the statute of limitations also necessitated filing suit before making a demand which, in any event, was futile, according to plaintiff. Plaintiff points out that the demand took place only 11 days after the filing of the original complaint and prior to the time defendants filed an appearance. Plaintiff also takes issue with the fact that defendants did not respond to the demand letter but, instead, filed the September 8, 2006 motion to dismiss. Given the lack of any prejudice to defendants, plaintiff urges this court to excuse the failure to make a demand before filing suit. Not only would dismissal result in prejudice and cause irreparable injury to plaintiff but it would result in a needless delay and a waste of judicial resources, according to plaintiff, because **[*21]** plaintiff would simply refile the same lawsuit after a dismissal without prejudice.

PSC's argument, adopted by the individual defendants, relies on the statutory text. PSC submits that a post suit demand does not comply with *section 7.42(1)* and that irreparable injury and other equitable concerns are confined to section *7.42(2)*, which allows a party to shorten the 90 day waiting period by showing irreparable injury.

HN5[↑] Both *Rule 23.1, Fed. R. Civ. P.* ("*Rule 23.1*"), and *section 7.42* contain demand requirements. *Rule 23.1* governs the pleading requirements of a shareholder derivative action in federal court. Gonzalez v. *Turul v. Rogatol Distributors, Inc., 951 F.2d 1, 2 (1st Cir. 1991)*. State law, in turn, governs the substantive requirements of demand. Id. (citing *Kamen v. Kemper Financial Services, Inc., 500 U.S. 90, 108, 111 S. Ct. 1711, 114 L. Ed. 2d 152 (1991)*); see, e.g., *In re IAC/Interactive Corporation Securities Litigation, 478 F.Supp.2d 574, 598 (S.D.N.Y. 2007)* (citing Kamen and finding that Delaware state law governs demand requirement for derivative section 10(b) and *Rule 10b-5* claims). In considering the contours of a demand and whether to excuse demand on the basis of futility, "a federal court must look to the **[*22]** law of the state of incorporation of the entity" sued, i.e., Massachusetts and the MBCA. *Forsythe v. Sun Life Financial, Inc., 417 F.Supp.2d 100, 109 (D.Mass. 2006)* (citing both *Gonzalez, 951 F.2d at 2*, and *Kamen, 500 U.S. at 97-108*); accord *Landy v. D'Alessandro, 316 F.Supp.2d 49, 57 (D.Mass. 2004)* ("law of the state of incorporation provides the circumstances under which demand would be futile"). [13]

HN7[↑] *Section 7.42* of the MBCA imposes a substantive demand requirement on shareholders seeking to bring derivative suits on behalf of a

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[13] ***HN6***[↑] With respect to the federal section 10(b) and Rule 10(b)(5) claims, application of the demand requirements of *section 7.42* is not inconsistent with the policies underlying the federal statute. "If federal courts were to fashion a demand requirement for federal claims, the existence of differing state and federal demand requirements would undermine the very purpose of the demand requirement" and result in "needless complexity." *RCM Securities Fund, Inc. v. Stanton, 928 F.2d 1318, 1327-1328 (2nd Cir. 1991)* (dismissing *Rule 10b-5* claim due to lack of demand based upon the applicable state law incorporated into the federal law); see *Kamen v. Kemper, 500 U.S. at 108* (reaffirming "basic teaching" of *Burks v. Lasker, 441 U.S. 471, 99 S. Ct. 1831, 60 L. Ed. 2d 404 (1979)*, that where "gap in the federal securities laws" exists, **[*23]** "federal courts should incorporate state law into federal common law unless the particular state law in question is inconsistent with the policies underlying the federal statute").

corporation. *Mass. Gen. L. ch. 156D, § 7.42*. Enacted in 2003, the MBCA became effective on July 1, 2004. *Mass. Gen. L. ch. 156D, §§ 1.01 et seq*. It was the "first comprehensive revision of Massachusetts law governing business corporations in approximately 100 years." Mass. Gen. L. ch. 156D, Comment to Introduction.

HN8[⬆] As in all statutory construction cases, the starting point is "'the language of the statute,'" *Phillips v. Pembroke Real Estate, Inc., 459 F.3d 128, 139 (1st Cir. 2006)*, to which this court now turns. See also *General Motors Corp. v. Darling's, 444 F.3d 98, 108 (1st Cir. 2006)* ("we 'examin[e] the plain meaning of the statutory language and consider [] the language in the context of the whole statutory scheme'"). "[I]f the language of a statute or regulation has a plain and ordinary meaning, courts need look no further and should apply the [statute or] regulation as it **[*24]** is written." *United States v. Lachman, 387 F.3d 42, 50 (1st Cir. 2004)*. Courts "'should look beyond the words of the statute to its history, policy or other extrinsic aids to ascertain statutory intent'" only when the language is ambiguous. *General Motors Corp. v. Darling's, 444 F.3d at 108* (quoting *Acadia Motors, Inc. v. Ford Motor Co., 44 F.3d 1050, 1055 (1st Cir. 1995)*, in parenthetical).

In the case at bar, the language of *section 7.42* is unambiguous. It reads as follows:

> ***HN9***[⬆] No shareholder may *commence* a derivative proceeding until:
>
> (1) a written demand *has been* made upon the corporation to take suitable action; *and*
>
> (2) 90 days have elapsed from the date the demand was made, or, if the decision whether to reject such demand has been duly submitted to a vote of the shareholders, not including the holders of those shares referred to in section 7.44(b)(3), **[*25]** within 60 days from the date when demand was made, 120 days have elapsed from the date the demand was made, unless in either case the shareholder has earlier been notified that the demand has been rejected by the corporation or irreparable injury to the corporation would result by waiting for the expiration of such 90-day or 120-day period.

Mass. Gen. L. ch. 156D, § 7.42 (emphasis added).

HN10[⬆] The plain and ordinary meaning of *section 7.42* requires the shareholder to make a written demand before he commences a derivative proceeding. The ordinary meaning of the term "commence" is to begin or start. Random House Dictionary of the English Language (2nd ed. 1987) (defining "commence" as "to begin; start"). The statute defines "derivative proceeding" as "a civil suit in the right of a domestic corporation." *Mass. Gen. L. ch. 156D, § 7.40*. Commencing a civil suit is commonly understood as filing a complaint in court or mailing the complaint with the filing fee to the clerk. See Mass. R. Civ. P. 3 ("civil action is commenced by (1) mailing to the clerk . . . a complaint and an entry fee . . . or (2) filing such complaint"); *Fed. R. Civ. P. 3* ("A civil action is commenced by filing a complaint with **[*26]** the court"). Filing an amended complaint does not "commence" a civil suit. Rather, it is part of a continuation of an ongoing, existing suit. Accordingly, the fact that plaintiff made a post suit demand, waited 90 days and then filed the amended complaint does not cure the original non-compliance with the plain language of *section 7.42(1)*. [14]

HN11[⬆] The drafters also chose to separate the two independent clauses in *subsections (1)* and *(2)* with separate numerical parentheses, a semicolon and a conjunctive link. See *Lopez-Soto v. Hawayek, 175 F.3d 170, 174 (1st Cir. 1999)* ("punctuation can provide valuable insights into statutory interpretation"); *Mosquera-Perez v. I.N.S., 3 F.3d 553, 556 (1st Cir. 1993)* ("had Congress intended two separate determinations, surely it could have

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[14] In addition, as explained infra, the 90 day waiting period is set forth in a separate section, i.e., *7.42(2)*, and lack of prejudice is not an excuse to non-compliance with *section 7.42(1)*.

made its intention plain, simply by writing [the statute] with 'two coordinate clauses joined by a conjunction'"). The drafters thereby intended to establish two separate requirements for a shareholder to satisfy before he could "commence **[*27]** a derivative proceeding." *Mass. Gen. L. ch. 156D, § 7.42*.

It is only the second subsection that contains the "irreparable injury" language. See *Charter Communications Entertainment I, DST v. Burdulis, 460 F.3d 168, 172-173 (1st Cir. 2006)* (noting the "general principle of statutory construction that" Congress presumed to act intentionally when it "includes particular language in one section of a statute but omits it in another section"). The comment clarifies that "irreparable injury" equates to "the entry of a preliminary injunction" and may include consideration of "factors . . . such as the possible expiration of the statute of limitations." *Mass. Gen. L. ch. 156D, § 7.42*, Comment; see Mass. Gen. L. ch. 156D, Introductory Comment ("Comments to the Act" provide "valuable tool in interpreting the Act"); *Mass. Gen. L. ch. 156D, § 1.50*, Comment (comments assist "courts to better interpret and apply the Act"). [15] Plaintiff's attempt to incorporate a statute of limitations prejudice argument as a means to avoid complying with the plain language of the first subsection ignores the rule that the drafters presumably acted intentionally when they omitted irreparable injury from the first subsection. **[*28]** See *Charter Communications Entertainment I, DST v. Burdulis, 460 F.3d at 172* (Congress presumed to act "intentionally and purposefully in the disparate inclusion or exclusion" of statutory language).

Similarly, the fact that plaintiff offered the board a stay does not excuse the failure to make a pre-suit demand. The plain language requires a demand prior to commencing suit. It does not make the offer of a stay an alternative means to satisfy the written demand requirement. Rather, this court may, in its discretion, enter a stay, an ability the drafters expressly accounted for in a separate section of the MBCA. *Mass. Gen. L. ch. 156D, § 7.43*.

Plaintiff's **[*29]** implied argument that the members of the board of directors are not disinterested or independent attempts to import a futility exception into *section 7.42*. [16] ***HN12***[⬆] The plain language of *section 7.42*, however, does not contain a futility exception. Interpreting the provisions of the MBCA, two courts in this district conclude that the statute eliminates futility as an exception to making a pre-suit demand upon the corporation. *In re Columbia Entities Litigation, 2005 U.S. Dist. LEXIS 33439 at **21-22 (D.Mass. Nov. 30, 2005)* (MBCA "does not waive the demand requirement for futility"); *Stegall v. Ladner, 394 F.Supp.2d 358, 367 (D.Mass. 2005)* (*section 7.42* "prevent[s] a demand futility defense"). Again, the drafters did not include an examination of the interest, disinterest or independence of the board as a factor to consider when examining whether "a written demand has been made upon the corporation." *Mass. Gen. L. ch. 156D, § 7.42(1)*. Instead, the drafters placed this inquiry in *section 7.44* in the context of whether to apply the business judgment rule's evidentiary presumption. See *Charter Communications Entertainment I, DST v. Burdulis, 460 F.3d at 172-173*.

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[15] When the meaning and language of the MBCA "is clear," however, or when "a [c]omment might be interpreted in a manner inconsistent with the language of the [MBCA], the language" of the MBCA controls. *Mass. Gen. L. ch. 156D, § 1.50*, Comment. The MBCA is based upon but not identical to the American Bar Association's Model Business Corporation Act ("the Model Act"), 1 Model Business Corporation Act Annotated (3rd ed. 1996). The comments reflect a number of the important differences and variations with the Model Act. Mass. Gen. L. ch. 156D, Comment to Introduction.

[16] Before July 2004, Massachusetts **[*30]** law allowed for a narrow exception excusing pre-suit demand on the basis of futility. See generally *Forsythe v. Sun Life Financial, Inc., 417 F.Supp.2d at 109* (summarizing the demand futility exception under Massachusetts law). The futility exception excused demand before or after filing suit "if there is a particularized showing that 'a majority of directors are alleged to have participated in wrongdoing, or are otherwise interested.'" Id. (quoting *Harhen v. Brown, 431 Mass. 838, 730 N.E.2d 859, 865 (Mass. 2000)*).

It is also worth pointing out that another court in this district concludes that section 7.42 requires a shareholder to make a pre-suit demand before commencing a derivative action. ING Principal Protection Funds Derivative Litigation, 369 F.Supp.2d 163, 170 (D.Mass. 2005) ("[t]here are no exceptions" to the pre-suit demand requirement in section 7.42). Like the courts in Stegall and Columbia, the court in ING dismissed the derivative claims due to the absence of a demand. Id.; Stegall v. Ladner, 394 F.Supp.2d at 367 (dismissing all federal and state law claims except for section 36(b) claim under Investment Company Act); In re Columbia Entities Litigation, 2005 U.S. Dist. LEXIS 33439 at * 22 (D.Mass. Nov. 30, 2005) **[*31]** (dismissing federal claim under Investment Company Act against corporate defendants organized under Massachusetts law because of the plaintiffs' failure to make a demand). Likewise, another court dismissed a federal section 36(b) Investment Company Act suit without prejudice because the "[p]laintiff did not tender a pre-suit demand to the [Federated Kaufman] Fund." Zucker v. Federated Shareholder Services, Co., 2007 U.S. Dist. LEXIS 15186, 2007 WL 709305 at * 4 (W.D.Pa. March 5, 2007) .

HN13[↑] Cases outside Massachusetts interpreting statutory provisions substantially equivalent to provisions in the Model Act provide guidance "in the absence of controlling Massachusetts precedent." Mass. Gen. L. ch. 156D, § 1.50 (interpretations by other courts of "substantially equivalent provisions" of corporate laws entitled to "significant weight" absent "controlling Massachusetts precedent"). Examining state statutory language identical to section 7.42(1), a number of these courts conclude that the statutes eliminate futility as an exception to making a written demand. [17] See Speetjens v. Malaco Inc., 929 So.2d 303, 308-310 (Miss. 2006); [18] McCann v. McCann, 138 Idaho 228, 61 P.3d 585, 591-593 (Idaho 2002); Allen ex rel. Allen & Brock Construction Company v. Ferrera, 141 N.C. App. 284, 540 S.E.2d 761, 764-766 (N.C.App. 2000). **[*32]** The Model Act also contains language identical to section 7.42(1), 2 Model Business Corporation Act Annotated (3rd ed. 1996), and, notably, the Model "[A]ct abolishes the futility exception to demand." Kamen v. Kemper Financial

[17] Delaware law retains the futility exception and is not a substantial equivalent to Massachusetts law. Cases applying Delaware law are therefore unpersuasive. A number of state legislatures, however, have adopted provisions substantially equivalent to section 7.42. See Ariz. Rev. Stat. § 10-742; Conn. Gen. Stat. § 33-722; Ga. Code Ann. § 14-2-742; Haw. Rev. Stat. § 414-173; Idaho Code Ann. § 30-1-742; Iowa Code § 490.742; Me. Rev. Stat. Ann. tit. 13-C § 753; Mich. Comp. Laws § 450.1493a; Miss. Code Ann. § 79-4-7.42; Mont. Code Ann. § 35-1-543; Neb. Rev. Stat. § 21-2072; N.H. Rev. Stat. Ann. § 293-A:7.42; N.C. Gen. Stat. § 55-7-42; R.I. Gen. Laws § 7-1.2-711; S.D. Codified Laws § 47-1A-742; Va. Code Ann. § 13.1-672.1; Utah Code Ann. § 16-10a-740(3); Wyo. Stat. Ann. § 17-16-742.

The Michigan case cited by plaintiff, Virginia M. Damon Trust v. North Country Financial Corporation, 325 F.Supp.2d 817 (W.D.Mich. 2004), to support **[*33]** the argument that dismissal creates a needless delay because plaintiff would refile suit (Docket Entry # 61, pp. 11-13), is distinguishable because the corporation in Damon Trust conceded pre-suit demand:

> NCFC acknowledged receipt of this letter when it petitioned the Court to appoint a disinterested person to investigate and assess whether the corporation should pursue the claims listed in the demand letter. NCFC stated: "While it appears that this letter does not comport with the requirements of M.C.L. § 450.1491a, NCFC nonetheless is prepared to accept the letter as a 'written demand . . . upon the corporation to take suitable action.'"

Virginia M. Damon Trust v. North Country Financial Corp., 325 F.Supp.2d at 822. In the case at bar, PSC has not similarly acquiesced in the failure to make a pre-suit demand.

Alternatively and with all due respect, the court in Damon simply ignores the plain language of the statute, a decision this court is not prepared to take, in favor of judicial economy. If the drafters of the MBCA intended to create an exception for judicial economy, they would have included the exception expressly in the statute.

[18] Plaintiff quotes a passage in Speetjens to support **[*34]** the argument that irreparable injury excuses demand. (Docket Entry # 90, pp. 9-10). Plaintiff, however, overlooks that the court described "irreparable injury" as an exception "where the shareholder has already been notified that demand has been rejected by the corporation." Speetjens v. Malaco, Inc., 929 So.2d at 309 (addressing and rejecting futility as an exception to the written demand statute). In the case at bar, plaintiff never waited for the company to reject a demand prior to filing suit.

Services, Inc., 500 U.S. at 105 n. 8.

Plaintiff next points out that there is no "prejudice whatsoever to Defendants." (Docket Entry # 61, p. 11). Plaintiff therefore asserts that dismissal is unwarranted. Lack of prejudice, however, is not the standard. ***HN14***[⬆] The plain language of *section 7.42(1)* provides that a plaintiff cannot commence a derivative action until "a written demand has been made" on the corporation. To borrow the language of a recent First Circuit case, "It is one thing to impose a gloss on the statute, such as the earmarking doctrine, that achieves formal compliance with the statute to rescue a transaction where no prejudice occurred. It is another to make lack of prejudice itself a substitute for formal compliance." **[*35]** *In re Lazarus, 478 F.3d 12, 17 (1st Cir. 2007)*.

Plaintiff further argues that "time was of the essence" both in the context of the statute of limitations and in the likelihood that board members would exercise additional outstanding back dated stock options. Even if time was of the essence, an exception not in the plain language of the statute, plaintiff could simply have made a pre-suit demand on the company, filed the original complaint shortly thereafter and then argued that "irreparable injury to the corporation" would take place by waiting the 90 day period. Subsection 7.42(2) allows for such a scenario. Inexplicably, however, plaintiff filed the original complaint and then the written demand 11 days later.

Plaintiff's complaint that the board did not respond to the August 28, 2006 demand letter also fails to justify non-compliance with *section 7.42(1)*. ***HN15***[⬆] The comment to the section unequivocally states that, "There is no obligation on the part of the corporation to respond to the demand." *Mass. Gen. L. ch. 156D, § 7.42*, Comment; accord Mass. Gen. L. ch. 156D, Introductory Comment ("Comments to the Act" provide "valuable tool in interpreting the Act").

HN16[⬆] Although not necessary in light **[*36]** of the statute's plain language, the policy of the statute confirms the conclusion that *section 7.42* requires a pre-suit demand. A demand allows the corporation to "protect the authority of the board of directors to decide whether to pursue a lawsuit on behalf of the corporation." *ING Principal Protection Funds Derivative Litigation, 369 F. Supp. 2d 163, 171 (D.Mass. 2005)* (characterizing this as " [t]he primary purpose of the universal demand statute"). The drafters concur that, "The [demand] rule is intended 'to give the derivative corporation itself the opportunity to take over a suit which was brought on its behalf in the first place, and thus to allow the directors the chance to occupy their normal status as conductors of the corporation's affairs.'" *Mass. Gen. L. ch. 156D, § 7.42*, Comment. Requiring the shareholder to make a written demand upon the corporation before filing suit gives the initial deference to the corporate body to manage the corporation's internal affairs. See generally *Grossman v. Johnson, 674 F.2d 115, 125 (1st Cir. 1982)* (similar purpose of demand requirement in *Rule 23.1* supported dismissal due to failure to make pre-suit demand). It also creates a simple rule **[*37]** thereby avoiding litigation regarding whether to excuse demand.

In sum, Massachusetts law, which applies to the substantive requirement of making a written demand upon the company, requires that plaintiff make a demand before filing suit. Plaintiff's failure to make such a demand is not cured by the August 28, 2006 demand made after filing suit and 90 days before filing the amended complaint. This court therefore recommends that the amended complaint be dismissed without prejudice to the substantive causes of actions. See *In re Kauffman Mut. Fund Actions, 479 F.2d 257, 267 (1st Cir. 1973)* (interpreting district court's dismissal "without prejudice" for failure to comply with *Rule 23.1* as "mean[ing] without prejudice to the substantive cause of action") ; see also Gonzalez v. *Turul v. Rogatol Distributors, Inc., 951 F.2d at 3* (reversing lower court and dismissing "complaint without prejudice" due to failure to comply with *Rule 23.1*); *Landy v. D'Alessandro, 316 F.Supp.2d 49, 75 (D.Mass. 2004)* ("First Circuit dismissals under

Rule 23.1 have been without prejudice"); see, e.g., *Zucker v. Federated Shareholder Services, Co., 2007 U.S. Dist. LEXIS 15186, 2007 WL 709305 at * 4 (W.D.Pa. March 5, 2007)* (dismissing count **[*38]** "without prejudice for failure to satisfy Massachusetts' universal pre-suit demand requirement").

CONCLUSION

Accordingly, in light of the above discussion, this court **RECOMMENDS** [19] that the motions to dismiss (Docket Entry # 46, 49, 51, 56, 57, 75 & 77) be **ALLOWED** and this action be dismissed without prejudice due to plaintiff's failure to make a pre-suit demand in accordance with *section 7.42*.

/s/ Marianne B. Bowler

MARIANNE B. BOWLER

United States Magistrate Judge

End of Document

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[19] Any objections to this Report and Recommendation must be filed with the Clerk of Court within ten days of receipt of the Report and Recommendation to which objection is made and the basis for such objection. Any party may respond to another party's objections within ten days after service of the objections. Failure to file objections within the specified time waives the right to appeal the order. *United States v. Escoboza Vega, 678 F.2d 376, 378-379 (1st Cir. 1982)*; *United States v. Valencia-Copete, 792 F.2d 4, 6 (1st Cir. 1986)*.

EXHIBIT B

Coordinated v. Johnson & Johnson

Superior Court of California, County of Los Angeles

November 17, 2017, Decided; November 17, 2017, Filed

JCCP No. 4872, Case No. BC628228

Reporter
2017 Cal. Super. LEXIS 8757 *

Coordinated Proceeding Special Title (Rule 3.550). Johnson & Johnson Talcum Powder Cases. Charmaine Lloyd, et al., Plaintiffs, v. Johnson & Johnson, et al., Defendants. This document pertains to: Plaintiff Elisha Echeverria, Acting Trustee of The 2017 Eva Elaine Echeverria Living Trust

Judges: **[*1]** Hon. Maren E. Nelson.

Opinion by: Maren E. Nelson

Opinion

AMENDED JUDGMENT

Dept.: 307

This action came on regularly for trial on July 24, 2017, in Department 307 of the above-referenced court, located at 600 South Commonwealth Avenue, Los Angeles, California, 90005, the Honorable Maren E. Nelson presiding. Plaintiff Eva Echeverria appeared through her attorneys Mark P. Robinson Jr., Kevin F. Calcagnie, Cynthia L. Garber, and others of Robinson Calcagnie Inc.; Helen Zukin of Keisel Law, LLP; and Allen Smith of the Smith Law Firm, PLLC. Defendants Johnson & Johnson ("J&J") and Johnson & Johnson Consumer Inc. (formerly known as Johnson & Johnson Consumer Companies, Inc.) ("JJCI") appeared through their counsel Bart H. Williams, Manuel F. Cachán, Susan L. Gutierrez, Lee M. Popkin, and others of Proskauer Rose LLP; Kimberly A. Dunne and others of Sidley Austin LLP; G. Greg Webb and others of Shook, Hardy & Bacon LLP; and Michael C. Zellers and others of Tucker Ellis LLP.

A jury of 12 persons was regularly impaneled and sworn. Witnesses were sworn and testified. The Court and jury heard evidence from July 26, 2017 through August 15, 2017. After hearing the evidence, the jury was duly instructed by the Court on August **[*2]** 16, 2017. Following arguments of counsel, the cause was submitted to the jury on August 16, 2017. The jury deliberated and thereafter returned a verdict on August 21, 2017, with its verdict attached hereto as Exhibit A. A judgment was entered on that verdict on August 21, 2017, and notice of said entry was served that same day.

After the death of Plaintiff Eva Echeverria on September 20, 2017, the parties submitted a stipulation and proposed order concerning substitution, and pursuant to that stipulation, the Court on October 12, 2017 substituted as Plaintiff Elisha Echeverria, Acting Trustee of The 2017 Eva Echeverria Living Trust.

On October 20, 2017, the Court signed and filed with the clerk its ruling (i) granting J&J's and JJCI's motions for judgment notwithstanding the verdict; and (ii) granting J&J's and JJCI's motions for new trial on the grounds of "(1) insufficiency of the evidence as to causation as to both defendants (Cal. Code of Civ. Pro. 657(6)); (2) error in law occurring at trial and excepted to by defendants (Cal. Code of Civ. Pro. 657(7); (3) misconduct of the jury (Cal. Code of Civ. Pro. 657(2); (4)

excessive compensatory damages (as to Johnson'& Johnson) and excessive **[*3]** punitive damages (as to both defendants) (Cal. Code of Civ. Pro. 657(5)." A copy of said ruling is attached hereto as Exhibit B. On October 20, 2017, the Court's ruling was also entered in the permanent minutes of the court, and a copy of said minutes are attached hereto as Exhibit C.

On October 30, 2017, the Court entered an order that "modified" the "specification of reasons" contained in the Court's aforementioned October 20, 2017 ruling, and a copy of said order is attached hereto as Exhibit D.

Pursuant to *Code of Civil Procedure, section 629, subdivision (b)*, where, as here, the court "grants [a] motion for judgment notwithstanding the verdict ... and likewise grants [a] motion for a new trial, the order granting the new trial shall be effective only if, on appeal, the judgment notwithstanding the verdict is reversed, and the order granting a new trial is not appealed from or, if appealed from, is affirmed."

NOW, THEREFORE, IT IS ORDERED, ADJUDGED AND DECREED:

The judgment entered on August 21, 2017 having been set aside by the Court's October 20, 2017 ruling, an amended judgment, notwithstanding the verdict, is entered as follows:

1. Judgment is entered in favor of Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc. and **[*4]** against Plaintiff Elisha Echeverria, Acting Trustee of The 2017 Eva Echeverria Living Trust on all claims in this case. Plaintiff Elisha Echeverria, Acting Trustee of The 2017 Eva Echeverria Living Trust, shall take nothing on all claims in this case.

2. Judgment is entered that Defendants Johnson & Johnson and Johnson & Johnson Consumer. Inc. are awarded their costs in the sum of $_ against Plaintiff Elisha Echeverria, Acting Trustee of The 2017 Eva Echeverria Living Trust.

DATED: November 17, 2017

/s/ Maren E. Nelson

Maren E. Nelson

Exhibit A

VERDICT FORM

We the jury in the above referenced case select the following:

1. ☒ Find in favor of Plaintiff Eva Echeverria and against Defendant Johnson & Johnson and award noneconomic damages in the amount of $68,000,000.

☐ Find in favor of Defendant Johnson & Johnson.

2. ☒ Find in favor of Plaintiff Eva Echeverria and against Defendant Johnson & Johnson Consumer, Inc. and award noneconomic damages in the amount of $2,000,000.

☐ Find in favor of Defendant Johnson & Johnson Consumer, Inc.

If you found in favor of Plaintiff Eva Echeverria against Defendant Johnson & Johnson above, do you:

3. ☒ Find in favor of Plaintiff Eva Echeverria and against Defendant **[*5]** Johnson & Johnson and award punitive damages in the amount of $340,000,000.

☐ Find in favor of Defendant Johnson & Johnson on punitive damages.

If you found in favor of Plaintiff Eva Echeverria against Johnson & Johnson Consumer, Inc. above, do you:

4. ☒ Find in favor of Plaintiff Eva Echeverria and against Defendant Johnson & Johnson Consumer, Inc. and award punitive damages in the amount of $7,000,000.

☐ Find in favor of Defendant Johnson & Johnson Consumer, Inc. on punitive damages.

Signed: August 21, 2017

/s/ Michael Maher Jr

PRESIDING JUROR

After this verdict form has been signed, notify the clerk, bailiff, or court attendant that you are ready to present your verdict in the courtroom.

Exhibit B

ORDERS REGARDING DEFENDANTS JOHNSON & JOHNSON CONSUMER, INC. AND JOHNSON & JOHNSON'S COMBINED MOTION FOR NEW TRIAL, DEFENDANT JOHNSON & JOHNSON CONSUMER, INC.'S MOTION FOR JUDGMENT NOTWITHSTANDING THE VERDICT, AND DEFENDANT JOHNSON & JOHNSON'S MOTION FOR JUDGMENT NOTWITHSTANDING THE VERDICT

I. BACKGROUND

A. Brief Overview of the Case

This case involves the first trial of claims by plaintiffs in coordinated proceedings contending they developed ovarian cancer as a result of their use of defendants' **[*6]** products (Johnson's Baby Powder and Shower to Shower)[1] in their perineal area. The products contain talc.

Plaintiff Eva Echeverria[2] ("Echeverria") testified that she began using Johnson's Baby Powder when she began menstruation in approximately 1965 at age 11 and used the product on a daily basis, and more frequently when menstruating, until 2016. She used Shower to Shower less frequently. She was diagnosed with high grade serous ovarian cancer in 2007. The action was filed July 26, 2016. An expedited trial was ordered given her medical situation and commenced July 21, 2017.

Prior to trial summary judgment was granted as to defendant Imerys Talc America, Inc. ("Imerys"), who supplied the raw talc for the products. The case went to trial against defendants Johnson & Johnson and JJCI. It was tried on a theory of negligent failure to warn.

The evidence showed that Johnson's Baby Powder was first sold in 1893. The evidence focused largely on epidemiological studies that show a statistical correlation between talc usage and ovarian cancer. The first study mentioning talc and cancer apparently was published in 1971 (Henderson, et. al.) but the study was not admitted into evidence. The only reference **[*7]** to it in the record is a citation to it in another study (Boorman 1994) (Ex. L-97) wherein Boorman reported that there was "some concern reported about the perineal exposure to talc and the occurrence of ovarian cancer in women...although other studies have failed to find such an association" and cited to Henderson. (Tr. 1271:25-1272:14.) The reports in evidence were to the effect that since at least 1982 there has been an ongoing debate in the scientific community as to whether talc usage may cause ovarian cancer or whether the science supported only a finding that there was a statistical association between talc use and cancer. The jury was called upon to resolve this complex scientific question.

B. A Brief Summary of the Law, the Evidence, and the Verdict

[1] The evidence at trial was that Johnson & Johnson manufactured talcum powder until 1967. Thereafter, the product, as well as Shower to Shower, was manufactured by Johnson & Johnson Consumer Inc. ("JJCI"). For purposes of this Order the defendants are referred to jointly except when separate reference is needed.

[2] Eva Echeverria died September 20, 2017. Her daughter, Elisha Echeverria, Acting Trustee of The 2017 Eva Elaine Echeverria Living Trust, was substituted as plaintiff on October 12, 2017. For ease of reading reference to "plaintiff" is to Eva Echeverria. No disrespect is intended.

In an action alleging that a product causes cancer, giving rise to a duty to warn, causation must be proven with a reasonable medical probability based upon competent expert testimony. Mere possibility alone is insufficient to establish a prima facie case.

> A possible cause only becomes 'probable' when, in the absence of other reasonable causal explanations, it becomes more likely than not that the injury was a result of its action. **[*8]** This is the outer limit of inference upon which an issue may be submitted to the jury. (See *Parker v. Employers Mutual Liability Ins. Co. of Wis. (Tex. 1969) 440 S.W.2d 43, 47*.)... With cancer the question of causation is especially troublesome....Under the present state of scientific knowledge...it is frequently difficult to determine the nature and cause of a particular cancerous growth....Although juries are normally permitted to decide issues of causation without guidance from experts, 'the unknown and mysterious etiology of cancer' is beyond the experience of laymen and can only be explained through expert testimony. (*Parker v. Employers Mutual Liability Ins. Co. of Wis., supra, at p. 46*.) Such testimony, however, can enable a plaintiff's action to go to the jury only if it establishes a reasonably probable causal connection between an act and a present injury.

Jones v. Ortho Pharm. Corp. (1985) 163 Cal. App. 3d 396, 403-404.

As discussed in further detail below, Echeverria's expert witnesses testified as to various epidemiological studies, as well as studies on animals, and opined as to general causation. Laura Plunkett, Ph.D. ("Plunkett") testified that in her opinion perineal use of talc can cause ovarian cancer. She characterized talc as a toxin that causes changes in cell formation that become cancerous over time and extended use, relying on studies that showed talc initiates an inflammatory **[*9]** response in cells, leading to the production of reactive oxygen species and changes in gene expression. (Tr. 1048:22-1051:23; 1009:3-1009:6; 1622:9-27; 1623-1624:25.)

John Godleski, M.D. ("Godleski"), testified that evaluation by electron microscopy showed talc was present in Echeverria's ovarian tissue.

Evidence was introduced that since at least 1982 (and possibly 1971 if the 1994 Boorman statements regarding Henderson's work are considered) several epidemiological studies showed a statistically valid correlation between talc exposure and ovarian cancer. Jack Siemiatycki, Ph.D. ("Siemiatycki") testified that in 2006 the International Agency for Research on Cancer ("IARC"), a division of the World Health Organization, categorized talc as "possibly" carcinogenic if used perineally. This term was defined to mean that "chance, bias, and confounding" could not be excluded as explaining the epidemiological results. IARC declined to find talc was a known or probable cause of ovarian cancer. (Ex. P-29; Tr. 1196: 7-23; 1198:8-1200:2; 2162:18-2163:10; 2282:5-2283:28; 2285:23-26; 2291: 15-23.) Siemiatycki, who chaired the IARC working group that classified talc as "possibly" carcinogenic, testified **[*10]** that in his view the present epidemiology results, including a pooled study (Terry 2013) sufficiently show a probable association between ovarian cancer and perineal talc use as that term is used by IARC (TR 2173:11-2176:19; 2401:22-28; 2412:20-2413:17) but conceded that the epidemiology was insufficient prior to 2007 to conclude that there was a causal association between perineal use of talc and ovarian cancer. (Tr. 2300:15-19; 2362:11-22.) Siemiatycki authored a paper to the same effect, published in 2008. (Ex. P-105; Tr. 2300:9-14.)

Numerous epidemiologic studies were put to the jury showing a range of "relative risk" ratios. Siemiatycki explained that "relative risk" is the ratio of the risk among persons exposed to the risk compared to the risk among the unexposed, explaining that "if the risk of cancer in the general population... is 4 percent in the general population but among a group of people with a certain environmental exposure it is 6 percent, the relative

risk of cancer due to that environmental exposure would be 6 percent divided by 4 percent equals 1.5." (Tr. 2126:17-2127:21.) He further explained that a ratio resulting in 2.0 is "the point at which the probability **[*11]** of causation, which is the probability that a given agent causes a specific disease, exceeds 50 percent ...." (Tr. 2434: 15-27.)

Annie Yessaian M.D. ("Yessaian"), Echeverria's treating physician, engaged in a "differential etiology" analysis and opined that that it was more probable than not defendants' products caused Echeverria's illness.

Echeverria emphasized at trial that condom manufacturers ceased using talc on their products in the 1990s. However, no admissible evidence was introduced suggesting that they did so because of information suggesting that talc was linked to ovarian cancer and the jury was instructed to disregard any such inference or suggestion.

Echeverria also introduced documents from defendants' files referencing a "talc/ovary problem" and documents that showed they engaged in efforts to persuade regulators and the scientific community, including the National Toxicology Program ("NTP") and IARC, that the studies were insufficient to conclude that talc was a probable cause of ovarian cancer, including evidence that Johnson & Johnson provided funding to a trade association known as the Cosmetics, Toiletry, and Fragrance Trade Association ("CFTA") and that it also took **[*12]** steps on its own to advance the debate in its favor.

Defendants introduced evidence there was no peer reviewed literature suggesting any causal mechanism (i.e. that extended use of talc caused inflammation leading to cancer). No published peer-reviewed articles have determined talc to cause ovarian cancer. (Tr. 2276:21-2277:19; 2280:2-10; 3695:19-3696:7; 3749:12-3750:1.) Further, defendants' experts testified to the effect that the epidemiology relied upon by Echeverria's experts, with four exceptions, discussed *infra*, showed a relative risk ratio of less than 2.0.

Defendants also showed that talc is not recognized as an ovarian cancer risk by the Centers for Disease Control or medical associations such as the American Congress of Obstetrics and Gynecologists or Society of Gynecological Oncology. (Tr. 2714:2-2721:9; 3580:9-3590:5.) The federal Food and Drug Administration has been requested to require manufacturers of talc powders to warn of a potential link to ovarian cancer but declined to do so. The most recent Physician Data Query published by the National Cancer Institute concluded that "[t]he weight of the evidence does not support an association between perineal talc exposure **[*13]** and an increased risk of ovarian cancer." (Tr. 1619:6-1620:8.) Although some manufacturers have recently placed a warning on their product and Imerys advised of IARC's 2006 findings on its Material Safety Data Sheet ("MSDS"), the evidence showed most manufacturers' products do not contain a warning today. There was no evidence of any warning by a manufacturer prior to 2007.

Defendants moved for nonsuit and a directed verdict, which were denied.

The jury was instructed based on *CACI 1222*, *430* and *431*, with additional special instructions. Those instructions required Echeverria to show that each defendant manufactured and sold Johnson's Baby Power and Shower to Shower to Echeverria and that prior to 2007 the products were dangerous or likely to be dangerous when used in a reasonably foreseeable manner, giving rise to an obligation to warn. The jury was also given Special Instruction No. 1 that required Echeverria to show that exposure to talc was a substantial factor in causing her illness by showing through expert testimony that there was a reasonable medical probability that talc causes ovarian cancer and a reasonable medical probability that it was a substantial factor in causing Echeverria's ovarian **[*14]** cancer. The jury was instructed under *CACI 103* that liability as to both actual and punitive damages was required to be shown as to each defendant separately. The jury was also instructed under *CACI 3945* as to the

burden of proof on punitive damages. Echeverria requested instructions on agency and alter ego liability. Those instructions were not given.

After a three week trial, including extensive expert testimony, the jury found in favor of Echeverria, awarding $68,000,000 in non-economic damages from Johnson & Johnson and $2,000,000 in non-economic damages from JCCI. It assessed $340,000,000 in punitive damages against Johnson & Johnson and $7,000,000 against JCCI.

Defendants move for new trial or for judgment notwithstanding the verdict ("JNOV").

C. Summary of Rulings and Orders

Mindful of the heavy burdens imposed on the moving parties, and the deference to be given to the jury's verdict, for the reasons that follow the Court concludes that defendants' trial motions should have been granted and now grants the defendants' motions for JNOV. It also grants defendants a new trial on the grounds of (1) insufficiency of the evidence as to causation as to both defendants (Cal. Code of Civ. Pro. 657(6)); (2) **[*15]** error in law occurring at trial and excepted to by defendants (Cal. Code of Civ. Pro. 657(7); (3) misconduct of the jury (Cal. Code of Civ. Pro. 657(2)); and (4) excessive compensatory damages as to Johnson & Johnson and excessive punitive damages as to both defendants (Cal. Code of Civ. Pro. 657(5)).[3]

II. JOHNSON & JOHNSON'S MOTION FOR JUDGMENT NOTWITHSTANDING THE VERDICT

A. Procedural Requirements and Legal Standard for JNOV Motions

A JNOV motion must be made within the time for filing and serving a notice of intention to move for new trial, and if a motion for new trial has been made the court is to rule on both motions at the same time. Cal. Code of Civ. Pro. §629(b). Notice of this motion was timely filed and the motion was argued concurrently with the new trial motion.

"The court . . . shall render judgment in favor of the aggrieved party notwithstanding the verdict whenever a motion for a directed verdict for the aggrieved party should have been granted had a previous motion been made." Cal. Code of Civ. Pro. §629(a). The power to grant judgment notwithstanding the verdict is the same as the power to grant a nonsuit or directed verdict, all of which are based on the legal sufficiency of the evidence. **[*16]** (*Beavers v. Allstate Ins. Co. (1990) 225 Cal.App.3d 310, 327-328*.) A motion for JNOV is akin to a demurrer to the evidence. Where a demurrer assumes all facts pleaded are true, a JNOV motion assumes all evidence supporting the verdict is true; the issue to be determined is whether such evidence constitutes a prima facie case. (*Moore v. San Francisco (1970) 5 Cal.App.3d 728, 733*.)

While evidence must be accepted as true and viewed in a light most favorable to the verdict, it must be substantial. (*Sweatman v. Dept. of Veterans Affairs (2001) 25 Cal.4th 62, 68*; *Osborn v. Irwin Memorial Blood Bank (1992) 5 Cal.App.4th 234*.) "'Substantial evidence' is not synonymous with 'any' evidence. To constitute sufficient substantiality to support the verdict, the evidence must be 'reasonable in nature, credible, and of solid value; it must actually be 'substantial' proof of the essentials which the law requires in a particular case.'" (*Id. at 284*, citing *Kruse v. Bank of America (1988) 202 Cal.App.3d 38, 51*.)

B. The Parties' Arguments

Johnson & Johnson argues that JNOV must be granted as there was no evidence that it

[3] The Court is also mindful that this case was prepared and tried in an expedited manner. Trial counsel, as well as JCCP liaison counsel, were required to do an extraordinary amount of work on behalf of their clients in a short period of time and are to be commended in this regard.

manufactured Johnson's Baby Powder or Shower to Shower. Further, it argues that if the evidence could be inferred to show that prior to 1967 it manufactured Johnson's Baby Powder there is no evidence to show it knew or should have known in the period 1965-1967 that talcum powder was linked in any way with ovarian cancer, as the first scientific work in this regard was published in **[*17]** 1982. It argues that as a matter of law it had no on-going duty to warn and further argues that it cannot be liable for the acts of its subsidiary absent a showing of agency or alter ego liability and that no such evidence was adduced.

Echeverria contends that witness Lorena Telofski ("Telofski"), designated as the "person most knowledgeable" by both defendants, as well as various experts and third parties, referred to "Johnson and Johnson" in their testimony without distinguishing between the two entities. She further contends that after 1967 Johnson & Johnson had knowledge that talc was the probable cause of ovarian cancer and thus had an on-going duty to warn consumers, notwithstanding that it did not manufacture the product because Johnson & Johnson "kept responsibility" over JCCI and directed it to manufacture the products, thereby justifying the imposition of liability against it.

C. The Evidence As To Johnson & Johnson

The uncontradicted evidence was that Echeverria used Johnson's Baby Powder beginning at age 11 (approximately 1965) and until 2016.

The evidence as to who manufactured the products at issue during that time period was limited and consisted of (1) an interrogatory **[*18]** asking the defendants "to state the first and last dates of sale of each product" it manufactured or sold that contained talc. The joint response stated that Johnson's Baby Powder "debuted" in 1893 and Shower to Shower debuted in the 1960s (Tr. 3111: 19-27); (2) an interrogatory stating JJCI is a wholly owned subsidiary of Johnson & Johnson existing since 1967 (Tr. 3111:2-3112:10); (3) testimony through Telofski that JJCI was responsible for the marketing and internal procedures and safety assessments of both products (Tr. 811:8-14; 812:27-813:23; 852:18-853:1; 861:27-862:10; 863: 18-22); and (4) demonstrative exhibits showing that the labeled packages show JJCI as the manufacturer of the products. (Ex. P-49; P-50).

The only document in evidence dated prior to 1967 was a 1964 memorandum. (P-343). That document discussed the development of a potential consumer research test with respect to a powder made with a cornstarch product called "Dry Flo." The penultimate paragraph states that a Johnson & Johnson employee (William Ashton) established that "the largest commercial uses of Dry Flo are...as a condom lubricant where it replaced talc because it was found to be absorbed safely in the **[*19]** vagina whereas, of course, talc was not." No witness was called to explain the meaning of this sentence, which is capable of two interpretations (whether talc was absorbed in the vagina at all or whether, if absorbed, it was "safely" absorbed). Echeverria argues this document is sufficient to show both that Johnson & Johnson manufactured the products at issue prior to 1967 and had a duty to warn and that it acted with malice in not doing so, supporting the verdict against it.

D. Analysis

(1) Duty to Warn

A duty to warn arises when a manufacturer fails to warn of facts that it knows or should know make a product likely to be dangerous. (*Trejo v. Johnson & Johnson (2017) 13 Cal. App. 5th 110, 131*, citing *Valentine v Baxter Healthcare Corp. (1999) 68 Cal. App. 4th 1467, 1482*.) As to Johnson & Johnson before a duty to warn could be imposed Echeverria was required to show that it manufactured the products at issue; that talc was the more likely than not cause of her ovarian cancer; and that Johnson & Johnson knew or should have known that talc probably would cause cancer.

In this regard a manufacturer will not be "charged with knowing more than what would come to light from the prevailing scientific or medical knowledge" at the time. (*Valentine, 68 Cal. App. 4th at 1483-1484*. *See also Anderson v. Owens-Corning Fiberglas Corp. (1991) 53 Cal. 3d 987, 1002* ["Negligence law in a failure-to-warn case requires a plaintiff to prove **[*20]** that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about."]; *Carlin v. Superior Court (1996) 13 Cal. 4th 1104, 1112*, (citing *Anderson*) ["Stated another way, a reasonably prudent manufacturer might reasonably decide that the risk of harm was such as not to require a warning as, for example, if the manufacturer's own testing showed a result contrary to that of others in the scientific community. Such a manufacturer might escape liability under negligence principles."])

Echeverria alleged that Johnson & Johnson designed, developed, manufactured, tested, packaged, promoted, marketed, advertised, distributed, labeled, and sold the products (Echeverria First Amended Complaint, ¶¶ 14, 18, 20, 21, 85, 94, 131), made specific advertising claims (Id. at ¶¶ 25, 26), have continuously advertised and marketed the products since the 1970s (Id. at ¶31), and failed to warn (¶¶ 89, 90).

After initially referring to both Johnson & Johnson and JJCI in the pleading, for the most part the two parties are jointly referred to as Johnson & Johnson. This is made clear in Paragraph 9 where, after introducing Defendant **[*21]** Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer, Inc.) as a wholly owned subsidiary of Johnson & Johnson, Echeverria indicates that the two companies will thereafter be referred to jointly as the "Johnson & Johnson Defendants." Echeverria did not allege any theory for holding the parent liable for the acts of the subsidiary (such as alter ego or agency), but instead alleges the same wrongful acts as to both. However, Echeverria did not establish this at trial.

Echeverria failed to put on direct evidence as to who manufactured the products in the period 1965-1967. The interrogatory response read into the record is ambiguous but taken together with Exhibit P-343 and the testimony of Telofski the jury could infer that Johnson & Johnson manufactured the product prior to 1967.

The sole evidence argued to impose a duty to warn on Johnson & Johnson that existed prior to 1967 is Exhibit P-343, authored in 1964. Interpreting the disputed sentence in the light most favorable to Echeverria, the document states only that talc was not "safely absorbed" in the vagina but does not discuss in any way the alleged consequences of that fact, i.e. that it was a probable **[*22]** cause of ovarian cancer. There was no showing that as of 1967 there was any suggestion by the scientific or medical community that talc was associated with ovarian cancer. And, no internal documents from the company prior to that date suggest that conclusion. Thus, one cannot infer from the document that Johnson & Johnson knew or should have known prior to 1967 that talc more probably than not caused ovarian cancer, such that any duty to warn of that fact arose at that time.

The further evidence at trial was that after 1967 JJCI manufactured the products at issue and was responsible for assessing their safety and determining whether warning labels should be put on them. At oral argument and in her briefing Echeverria conceded that the documents and evidence showed that Johnson & Johnson ceased making Johnson's Baby Powder in 1967. However, she argues that because Johnson & Johnson called no witness to show that Johnson & Johnson's "involvement" with talc products ended in 1967 the jury could infer that Johnson & Johnson was liable for failure to warn. (Echeverria's Opposition to Johnson & Johnson's motion for JNOV at page 2, lines 24-25.)

This argument fails. Echeverria bore the burden **[*23]** of proof on this issue. She presented

no evidence to contradict Telofski's testimony or the demonstrative exhibits. The law is well-established that a holding company ordinarily cannot be held liable for the acts of its wholly owned subsidiary absent a showing of agency or alter ego liability. (*Sonora Diamond Co. v. Superior Court (2000) 83 Cal.App.4th 523, 538-540*.) "As a practical matter, the parent must be shown to have moved beyond the establishment of general policy and direction for the subsidiary and in effect taken over performance of the subsidiary's *day-to-day* operations in carrying out that policy." (*Id. at 542*, emphasis in original.)

While evidence was introduced that JCCI is a wholly owned subsidiary of Johnson & Johnson, no evidence was adduced as to why JCCI was created; that JCCI was created to make the products on behalf of Johnson & Johnson; who JCI's officers and directors are or whether they overlap with Johnson & Johnson's; that JCCI is undercapitalized; that Johnson & Johnson controlled JCCI's day-to-day operations, nor any other evidence suggesting that an alter ego or agency theory could be put to the jury. Further, the jury was not instructed on these theories of liability as the evidence adduced was insufficient to support such instructions. **[*24]**

Echeverria argues that Telofski, who was designated as the person most knowledgeable for both Johnson & Johnson and JJCI (Tr. 800:11-18), distinguished between the two companies on only three occasions in her testimony. (Id. at Tr. 801:23-802:4; 804:7-19; 813:10-23.) She argues that for the vast majority of her testimony, Telofski used the words, "Johnson & Johnson." Echeverria, however, does not indicate the subject matters on which Telofski was designated to testify. Further, Echeverria's counsel was aware when Telofski's deposition was taken that Telofski was an employee of JJCI and that there were two separate corporations. To the extent counsel asked questions regarding Johnson & Johnson, Telofski properly answered them on behalf of that entity.

Finally, Echeverria notes the experts all referred to "Johnson & Johnson." That experts or third parties referred to "Johnson & Johnson" does not save the verdict. None were asked to opine that Johnson & Johnson (as opposed to JCCI) manufactured or distributed the products after 1967 and indeed it was not shown that any would have had such knowledge.

Apparently recognizing that the oral testimony does not support a finding that Johnson & **[*25]** Johnson manufactured or distributed the products after 1967 Echeverria orally argued that Johnson & Johnson "hired someone" (JCCI) to make the products for it after 1967 but "kept responsibility" for them, thereby imposing on Johnson & Johnson responsibility for placing a warning on the products at all times. The documentary evidence and oral testimony that support these factual assertions is not of a quality sufficient to sustain the verdict.

First, and as noted above, there was no evidence that Johnson & Johnson "hired" JCCI to make products for it. Further, the documents do not support an alter ego or agency theory of liability. The documents may be grouped into several categories: those written by Johnson & Johnson employees evidencing consideration of the marketing opportunities and obstacles for talc (Ex. P-9 and Ex. P-10); documents showing that Johnson & Johnson sought to assert its views in the scientific community as to what the scientific evidence showed vis-a-vis talc (Ex. P-16, P-20, P-59, P-204, P 261 through P-264, P2-66, P-267); those that Echeverria argues show that Johnson & Johnson declined to fund studies into research concerned with the possible link between talc **[*26]** and ovarian cancer or would fund only if favorable results would be guaranteed (Ex. P-55, P-262); and those that show that condom manufacturers and Imerys either ceased using talc in their products or warned about its potential harm (Ex. P-19, P-27, P-396). In addition, Echeverria argues that a document written by a JCCI employee shows that after 1967 Johnson & Johnson should be liable for its' subsidiary's failure to warn (Ex. P-764).

Considered individually or as a whole, and drawing all inferences in support of the verdict, these documents could not be read by the jury as giving rise to a duty to warn on the part of Johnson & Johnson after 1967.

The document on which Echeverria primarily relies to show that Johnson & Johnson was "responsible" for JCCI is Exhibit P-764, dated January 11, 1994. This is a draft document (not on letterhead) entitled "Talc Questions and Answers" that posed various questions and answers regarding the state of knowledge regarding scientific research on the issue of the linkage between talc and cancer and responding to various studies to date. The evidence at trial was that this document was drafted by Don Jones who was in the research and planning group **[*27]** at JCCI. (Tr. 895:22-896:12; 902:4-19.) It made various references to Johnson & Johnson's decisions regarding its labeling of Johnson's Baby Powder, indicated "Johnson & Johnson uses the highest standards in making its baby powder," and stated "Johnson & Johnson had joined independent researchers and the government in testing talc and that no link with cancer was found."

No showing was made as to what use, if any, the draft document was put. There was no showing that Johnson & Johnson expressly or impliedly authorized these statements. Jones was not called to testify and did not indicate the facts on which he based the statements related to "Johnson & Johnson." In short, that a JCCI employee of unknown authority stated in a draft document that "Johnson & Johnson" made decisions regarding labeling of the product or used the highest standards in makings "its" baby powder or engaged in research is insufficient to show, as a matter of law, that Johnson & Johnson in fact manufactured and labeled the product or "kept responsibility" for JCCI after 1967. (*Young v. Horizon West, Inc. (2013) 220 Cal.App.4th 1122, 1133*; *van't Rood v. County of Santa Clara (2003) 113 Cal. App. 4th 549, 571)*.

As to Johnson & Johnson's own acts, the assertions by Echeverria that Johnson & Johnson employees considered marketing obstacles **[*28]** for talc based products is insufficient to create an inference that Johnson & Johnson was liable for the acts of its subsidiary after 1967.

Exhibit P-9, a 1986 memo from Ashton's files referenced the fact that "safety of cosmetic powders has been a concern, especially among health professionals. They have decided that powders provide no health benefit. Therefore, the potential for harm from respirables or accidental exposure should be avoided. Mothers are now being advised not to use baby powder, especially talc baby powders." The document goes on to say that "retrospective studies have implicated talc use in the vaginal area with the incidence of ovarian cancer. While a CFTA sponsored animal study has shown talc does not migrate, this concern does affect use of powders for adult women.... Based on the scientific evidence and extensive experience and use we believe that cosmetic powders are safe for use in babies and adults." The document observes that Johnson & Johnson holds patents for segregation of "super talc" and a cornstarch products well as other patents and concludes that "J&J" is probably working at the limits of cosmetic powders technology and "must pursue technologies which **[*29]** will provide a proven health benefit for use of powders on babies." It also noted that it was possible to hypothesize that "pursuit of technologies which would create talc based powders of higher interest (than JBP) to adults could be profitable."

No evidence was adduced as to why this document was written or to whom (if anyone) it was sent. Fairly read it suggests that a scientist at Johnson & Johnson (Ashton) was suggesting that baby powder use was impacted by the health community and that Johnson & Johnson might in the future pursue technologies to increase the use of cosmetic powders. It could not be fairly inferred from this document that Johnson & Johnson controlled JCCI, or "kept responsibility" for it.

Likewise, Exhibit P-10, a memo dated August 5, 1992, from a Johnson & Johnson file but without testimony as to its author or recipients, indicated that an obstacle to marketing the product was "negative publicity from the heath community on talc (inhalation, dust, negative doctor endorsement, cancer linkage)" and recommended investigation of an additive to reduce dust. But, the document's vague reference to negative publicity from a "cancer linkage," without more, was insufficient **[*30]** for a jury to find Johnson & Johnson "kept responsibility" for JCCI.

Nor are documents referencing the funding of studies sufficient to impose liability on Johnson & Johnson. Exhibit P -55 was heavily relied upon by Echeverria. It is a 1975 memo on Johnson & Johnson letterhead documenting that an employee named Gavin Hildick-Smith sent a "small donation" to Keith Griffiths of the Tenovus Institute for Cancer Research in Cardiff, England and suggesting that "it might be of value to identify the precise scientific data available to Tenovus concerning talc and ovarian cells." A handwritten note attached by D. Petterson inquired as to whether Hildick-Smith advised in advance of this donation and opined that the donation "has certainly given Griffiths the opening to put us on notice of the talc/ovary problem." Other than adducing testimony that Hildick-Smith was a doctor and Johnson & Johnson employee (Tr. 883:19-28) no evidence was introduced as to the capacities of any of the employees receiving the memo, or the role of "D. Petterson" at Johnson & Johnson or the meaning of the term "talc/ovary problem." Nor was there any showing that Griffiths ever had or provided any research to Johnson **[*31]** & Johnson which might have actually put it on notice of a "talc/ovary problem," let alone that Johnson & Johnson controlled JCCI.

Nor does Exhibit P-262 support Echeverria's argument. This e-mail chain indicates Johnson & Johnson would financially support "the Huncharek/Muscat narrative on ovarian cancer" but was not "Yet" prepared to support a "diaphragm/ovarian epidemiological study." That Johnson & Johnson declined to fund research could not be inferred by the jury to support a finding that it controlled JCCI.

Exhibits P-57 and P-27 are also insufficient to impose liability on Johnson & Johnson for acts taking place after 1967. Exhibit P-57 is an agreement by Johnson & Johnson dated June 4, 1994 guaranteeing funding of $10,000 to CFTA for the "management, coordination, and development of scientific data ...pertaining to the safe use of talc," agreeing to indemnify CFTA with respect to same, and further acknowledging that any CFTA reports "will become public documents." While this document clearly indicates Johnson & Johnson sought to bring to the public's attention its views regarding the safety of talc it cannot be said, by inference or otherwise, that it demonstrated that Johnson **[*32]** & Johnson exercised day-to day control over JCCI sufficient to implicate the doctrines of alter ego or agency. Similarly, that either Johnson & Johnson or JCCI sought to bring their views forward either on their own or through CFTA, to IARC and others in the scientific community (Ex. P-16, P-20, P-59, P-204, P-238, P-261-264, P-266, P-267) and strategized about how to do so did not create evidence that Johnson & Johnson controlled JCCI to such an extent as to make it liable for JCCI's decisions.

Documents from third parties also could not be relied upon to meet Echeverria's burden of proof Exhibit P-16 to JCCI from a consultant (Wehner) suggesting that Johnson & Johnson point out to the FDA the flaws in a proposed study and decline to fund same and Exhibit P-16 from Wehner to JCCI criticizing the manner in which CFTA analyzed certain data and noting that its inaccuracies subject the industry to being perceived as the cigarette industry also could not be used by the jury to infer that Johnson & Johnson was "responsible" for JCCI. As an initial matter, Wehner goes on to state that the public perception "would be a particularly tragic misperception in view of the fact that the industry **[*33]** does have powerful, valid

arguments to support its position." More importantly, that a third party consultant advised JCCI as to what he believed its parent should do vis-à-vis the CFTA does and cannot establish that Johnson & Johnson is liable for warnings on products it did not make or distribute. (*Young v. Horizon West, Inc. 220 Cal.App.4th at 1133*; *van't Rood v. County of Santa Clara 113 Cal. App. 4th at 571*).

Similarly, Exhibit P-27, from Imery's Director of Product Safety, to Ashton, cautioning that IARC could classify talc as potentially carcinogenic and suggesting that Ashton counsel his management regarding same, as well as Exhibit P-396 between the same two persons, transmitting an April 2004 scientific paper which the Imery's employee characterized as "compelling" evidence of a theory as to how talc could cause ovarian cancer and cautioning that the NTP could classify talc as a "causative agent" based thereon cannot be the basis for liability against Johnson & Johnson. A third party (Imerys) cannot create a relationship showing that Johnson & Johnson had "responsibility" for JCCI, any more than the acts of a purported agent suffice to show a principal-agent relationship. (Id.)

Finally, the fact that Johnson & Johnson was aware that condom manufacturers discontinued the use of **[*34]** talc in its products in 1994 (Ex. P-19) or that Imerys put a warning on its MSDS (Ex. P-37) in 2006 does not establish that talc was known or should have been known to cause ovarian cancer prior to 2007 or that Johnson & Johnson was "responsible" for JCCI thereby. As to the condom issue, Echeverria introduced evidence that another of her experts (Plunkett), in her report, relied on a 1994 newspaper article that opined that condom manufacturers removed talc from their products "in part due to ovarian cancer concerns." No evidence was admitted, however, as to what those concerns were (i.e. whether the condom industry ceased. to use talc because the available science supported a conclusion that talc was a *probable* cause of ovarian cancer or because the concerns surrounded publicity of the *possibility* of such a link) and the jury was specifically instructed that the facts set forth in the article were not admitted for their truth. As such, evidence as to what the condom industry did could not have properly been considered by the jury to establish knowledge on the part of Johnson & Johnson, much less determine it was "responsible" for JCCI's decisions regarding warnings. Likewise, the decision **[*35]** by Imerys in 2006 to put a statement on its MSDS that restated IARC's 2006 conclusion that talc was a "possible" carcinogen could not be used to show that in 2007 Johnson & Johnson had a duty to warn, or that it was responsible for JCCI.

Following oral argument on these motions Echeverria argued for the first time (in supplemental papers filed October 13, 2017 and not authorized by the Court but nonetheless considered) that Johnson & Johnson had an on-going duty to warn consumers and to recall the products. The cases cited by Echeverria, however, stand for the proposition that a manufacturer of equipment *who continues to market the equipment* and determines it is likely to be dangerous has a duty to recall the product or retrofit it. (*Hernandez v Badger Constr. Equip Co. (1994): 28 Cal. App. 4th 1791, 1827*; *Lunghi v Clark Equip. Co. Inc. (1984) 153 Cal. App. 3d 485, 494*.) Echeverria cites no authority for the proposition that a manufacturer who has ceased to make the product must cause a warning to be placed on the product by another manufacturer or cause that manufacturer to recall the product. Moreover, Echeverria did not ask the jury to be instructed on this basis under *CACI 1223* or otherwise and cannot assert it for the first time after oral argument on post-trial motions.

(2) Punitive Damages

As to punitive damages Echeverria **[*36]** was required to show by clear and convincing evidence that Johnson & Johnson acted with malice, i.e. "despicable conduct which is carried on by the defendant with a willful and conscious disregard of the rights and safety of others." *Cal. Civ. Code §*

3294 subd. (c)(1).

> The term "'despicable,'" though not defined in the statute, is applicable to "circumstances that are 'base,' 'vile,' or 'contemptible.'" (College Hospital Inc. v. Superior Court (1994) 8 Cal.4th 704, 725 [34 Cal. Rptr. 2d 898, 882 P.2d 894], quoting 4 Oxford English Dict. (2d ed. 1989) p. 529.) Under the statute, "malice does not require actual intent to harm. [Citation.] Conscious disregard for the safety of another may be sufficient where the defendant is aware of the probable dangerous consequences of his or her conduct and he or she willfully fails to avoid such consequences. [Citation.] Malice may be proved either expressly through direct evidence or by implication through indirect evidence from which the jury draws inferences. [Citation.]" (Angie M v. Superior Court (1995) 37 Cal.App.4th 1217, 1228 [44 Cal. Rptr. 2d 197].)

Pfeifer v. John Crane, Inc. (2013) 220 Cal. App. 4th 1270, 1299.

Because Johnson & Johnson is a corporate defendant Echeverria was also required to show by clear and convincing evidence that a director or managing agent acted with malice. Cal. Civ. Code, § 3294, subd. (b). "A plaintiff may satisfy the 'managing agent' requirement of Civil Code section 3294, subdivision (b), through evidence showing the information in the possession of the corporation **[*37]** and the structure of management decisionmaking that permits an inference that the information in fact moved upward to a point where corporate policy was formulated. These inferences cannot be based merely on speculation, but they may be established by circumstantial evidence, in accordance with ordinary standards of proof." (Romo v. Ford Motor Co. (1999) 99 Cal. App. 4th 1115, 1141, disapproved on other grounds in People v. Ault (2004) 33 Cal. 4th 1250.)

The only employee of Johnson & Johnson referenced in the pre-1967 documents that Echeverria contends support punitive damages against Johnson & Johnson was William Ashton. There was no showing as to Ashton's capacity at Johnson & Johnson sufficient to support a punitive damage award. The testimony offered by Telofski was that Ashton was deceased, had retired some years earlier, and was in "research and development" at the time he left the company. Telofski testified she was "not sure if he was a manager or director level" when he left the company. Telofski went on to say she "really just doesn't know." (Ex. 1 and 2 to Defendants' Compendium of Trial Transcripts.) No questions were asked as to Ashton's position in 1964.

Post 1967 the only Johnson & Johnson employees identified were Neal Matheson, who signed Exhibit P-57 in 1994 **[*38]** and was Executive Vice President of Research & Development and identified by Telofski as a "vice president in R & D" (Tr. 805:25-27) and Steve Mann, who "worked" at Johnson & Johnson (Tr. 805: 15-17) and whose title was shown as "Director, Toxicology." Mann communicated regarding funding the "Huncharek/Muscat study" (Exhibit P-262) and Matheson and Mann exchanged e-mail correspondence regarding the CFTA Task Force and steps Johnson & Johnson might take to bring its views to the attention of IARC and others in the scientific community and monitored IARC's conclusions (Exhibits P-204, P-261 through P-264, P-266, P-267). Assuming that the jury could infer that these persons were managing agents of Johnson & Johnson there was no showing that either engaged in manifest disregard of safety or was reckless in not causing Johnson & Johnson to warn that talc was a "probable" cause of cancer. The best that can be said from the evidence is that they were aware IARC classified talc as "possibly" carcinogenic, a standard insufficient as a matter of law to require any warning, even had Johnson & Johnson been the manufacturer of the product.

In short, there was simply no evidence that Johnson & Johnson **[*39]** knew in the 1965-1967 time

period that talc more likely than not caused ovarian cancer, giving rise to a duty to warn, much less that a managing agent acted with requisite malice in failing to give the warning. Nor is the verdict saved by reference to argument that documents existing after 1967 can create a basis for liability as to Johnson & Johnson based on JCCI's failure to warn. The documents and testimony, granting all inferences in favor of Echeverria, as a matter of law do not support liability on an agency or alter ego theory, much less support a finding by clear and convincing evidence that a punitive damage award was appropriate. For these reasons alone the JNOV motion must be granted as to Johnson & Johnson.

Further, and as discussed below, Echeverria failed to meet her burden of proof to show that her use of Johnson's Baby Powder and Shower to Shower were the probable cause of her ovarian cancer. Thus, as to both Johnson & Johnson and JCCI the motion for JNOV must be granted.

III. JCCI'S MOTION FOR JUDGMENT NOTWITHSTANDING THE VERDICT

A. Summary of the Argument

Defendants advance three arguments as to why JNOV must be granted based on the argument that Echeverria failed to **[*40]** present evidence sufficient to show that her use of talc based products was the probable cause of her ovarian cancer. Specifically, they argue that Echeverria's specific causation expert, Yessaian, failed to present epidemiology showing talc was the more probable than not cause of her cancer and used an improper methodology for determining the cause of her cancer (differential etiology) given the lack of epidemiology. JCCI also argues that no substantial evidence was presented to show that it had a duty to warn prior to 2007 and that as a result JNOV on both the general and punitive damage awards must be granted.

Echeverria contends that the motion is not well taken, as she had no obligation to present epidemiologic evidence. She further argues that Yessaian properly engaged in a differential etiology. She argues further that other experts (Plunkett, Godleski, Siemiatycki) established general causation. Finally, she argues that internal documents pre-dating 2007, discussed supra, showed that genital use of talc was not safe and knew that others in the industry warned of its dangers, supporting the punitive damage award against JCCI.

B. The *Sargon* Ruling and a Summary of Yessaian's Testimony [*41]

In evaluating defendants' causation arguments, background concerning the general causation testimony that was offered is necessary, as is an understanding of the permitted scope of Yessaian's testimony.

Prior to trial defendants made a series of motions under *Sargon Enterprises, Inc. v. University of Southern Cal. (2012) 55 Cal.4th 747* to exclude various expert testimony. Certain general causation experts were excluded and the testimony of others was limited. A written order issued, as did an oral clarification. (Tr. of July 18, 2017 at 5: 23-6:27.) Yessaian was permitted to opine that, using a "differential etiology methodology," it was "more probable than not" that Echeverria's cancer was caused by her use of talc based on Echeverria's medical history; the fact that talc was found in her ovarian tissue; 4 epidemiological studies involving women using talcum powder who were diagnosed with ovarian cancer which showed an "odds ratio" in excess of 2.0 thus permitting Yessaian to "rule in' talc as a causative agent; and other studies generally showed an odds ratio of 1.22 to 1.39. She was not permitted to testify that inflammation of cells was involved in Echeverria's cancer.

The testimony at trial by Yessaian on specific causation was to the effect that her methodology **[*42]** in determining the probable cause of Echeverria's cancer was to engage in a

"differential diagnosis," or "differential etiology," (Tr. 2609:16-18.) She explained that this process involved identifying risks for a disease; ruling out risk factors that you don't believe apply; and ruling in what you believe is the cause of the cancer. (Tr. 2812:18-21.) She testified that she ruled out 13 other potential known risk factors for ovarian cancer that could be applicable to Echeverria (genetics; history of family members with cancer at an early age or breast or ovarian cancer; early onset of menarche; age, age at menopause; obesity; polycystic ovarian syndrome; endometriosis; tobacco and alcohol use; use of hormone replacement therapy) and considered "protective factors" (number of pregnancies and births; breast feeding; use of birth control pills; tubal ligation) (Tr. 2647:9 - 2648:18). She testified she considered talc use a risk factor based on epidemiological studies as well as the number of applications of talc Echeverria had, which she estimated to exceed 30,000 and the number of years of talc usage prior to diagnosis (32) (Tr. 2612:15 - 2613:2) and also considered the "mechanism" by **[*43]** which it is theorized that talc migrates to the ovaries, the fact that talc was found in Echeverria's ovarian tissue, and the literature suggesting that talc exposure causes cancer by inflammation that ultimately leads to malignant transformation of cells (Tr. 2613:10 - 2614:11; 2618:3-2618:25; Tr. 2611:11 - 2612:4; 2621:21-2630:6; 2675:8-2676:21).

As to the testimony that inflammation was considered the mechanism by which talc caused Echeverria's cancer, the opinion including that testimony was stricken as no inflammation was found in Echeverria's tissue. (Tr. 2645: 18-20.) Yessaian then testified more generally that she considered the mechanism by which talc is hypothesized to cause ovarian cancer is by way of inflammatory processes. (Tr. 2646: 1-9.)

In reaching her conclusion that talc was a risk factor to be considered Yessaian relied on four epidemiologic studies (Cramer 1982; Rosenblatt 1992; Cramer 1999; and Wu 2009) that showed odds ratios in excess of 2.0 that a woman using talc would develop ovarian cancer (i.e. that she had 50% or greater chance of developing cancer than women who did not use talc), as well as 26 case controlled studies, 5 cohort studies showing "odds ratios" **[*44]** of 1.2 or 1.3, which she opined showed that the women in those studies had a "trend of thirty percent increase in risk," and meta-analysis and pooled analysis (Tr. 2658:5-12; 2820: 6-28; 2818:1-15). Yessaian admitted at trial that she knows of no studies showing a risk ratio over 2.0 for serous invasive ovarian cancer, which is the type of cancer with which Echeverria was diagnosed (Tr. 2896:1-2897:16) and that one study on which she relied (Cramer 1999) showed an odds ratio of 1.70 for serous ovarian cancer (Tr. 2672: 6-20) and a second (Wu 2009) also showed an odds ratio of 1.70 for serous ovarian cancer (Tr. 2672:21-2673:5). She interpreted those results as a 70% increased risk (Tr. 2896: 12-13.) She further testified that other studies on which she relied that showed an odds ratio of less than 2.0 were useful because they showed an increased risk of cancer developing in talc users and testified that specific studies showed this. She testified a study by Gertig (2000) showed a 1.4 odds ratio and interpreted this as meaning the subjects had a 40% increase in risk for serous ovarian cancer in women using talc (Tr. 2668:12-2669:19) and that a study by Gates (2008) showed an odds ratio **[*45]** of 1.6, which she interpreted as meaning that women who used talc had a 60% increase in the risk of developing serous ovarian cancer compared to those who did not (Tr. 2669:20-27) and that a "pooled" study by Terry (2013) had an "odds ratio" of 1.20 for serous ovarian cancer, which she interpreted as translating to a 20% increase in risk (Tr. 2670:11-15). She further acknowledged that Wu (2009) showed that a person with genital use of talc with 15,600-52,000 applications showed an odds ratio of 1.34 and acknowledged that the number was statistically insignificant (Tr. 2910: 21-25).

Yessaian also testified that because Echeverria was obese the estrogen effects of an increased body mass index might serve in combination with other factors to increase her ovarian cancer risk (Tr.

2870: 24-26) but stated that obesity more probable than not did not contribute to her cancer because elevated BMI is not associated with high grade serous ovarian cancer. (Tr. 2866: 16-22.) She testified she "ruled out" age as a possible cause of cancer although "it could have gone either way." (Tr. 2870:19-21.) She admitted that Echeverria's risk of ovarian cancer was increased by her number of ovulations but **[*46]** stated it was "less likely than not." (Tr. 2881:15-22.) She acknowledged that cancer is "multifactorial" (Tr. 2875: 4-10) and admitted that when she "ruled" out risk factors she ruled them out because it was "less than 50 percent likely that they were the factor." (Tr. 2883: 18-19).

She further testified that although many cancers have no known cause, she did not "rule out" unknown causes and that it was not possible to do so. After admitting idiopathic causes are the leading cause of ovarian cancer and that it was probable Echeverria's cancer was caused by some risk factor science does not yet know about (Tr. 2864:26-2688:27), Yessaian testified that there was less than a 50% chance Echeverria's cancer was idiopathic. (Tr. 2888:19-26; 2890:28-2891:1; 2894:13-18.) However, she could not put a "percentage" on how less likely that was (Tr. 2894: 20-21.)

C. Analysis

Following trial if the Court is convinced that there is no substantial conflict in the evidence and that the tendered expert opinions do not show specific causation (which, under *Jones v Ortho. Phar. Corp. (1996) 163 Cal. App. 3d 396*, must be shown by expert testimony in a case alleging cancer) a JNOV is properly granted. *See Osborn v. Irwin Mem'l Blood Bank (1992) 5 Cal. App. 4th 234, 275*. After considering it in totality and weighing all inferences **[*47]** in favor of Echeverria, the Court is persuaded that Yessaian' is opinion is insufficient as a matter of law to support the verdict.

(1) Specific Causation Was Not Shown

(i) Yessaian Did Not Have a Basis to "Rule In" Talc

Yessaian was the only expert called on specific causation. She did not rely on the testimony of Plunkett or Siemiatycki in forming her opinions. Thus, while the jury could well have evaluated the credibility and reliability of her opinions by comparing them to information provided by Plunkett and Siemiatycki, her determination that talc was a cause of ovarian cancer and was the "more probable than not" cause of Echeverria's cancer is dependent only upon her testimony and that of Godleski. As to the latter, there was no dispute that he testified to locating talc in Echeverria's pathology tissue. Thus, the evidence is not in conflict.

In conducting a differential etiology[4] Yessaian was required first to establish talc is a probable cause of ovarian cancer. Without establishing that fact, she could not "rule in" talc as a probable cause of Echeverria's disease. As Yessaian explained, and as case law makes clear: "In performing a differential diagnosis, a physician begins by **[*48]** 'ruling in' all scientifically plausible causes of the plaintiff's injury. The physician then 'rules out' the least plausible causes of injury until the most likely cause remains. The final result of a differential diagnosis is the expert's conclusion that a defendant's product caused (or did not cause) the plaintiffs injury." (*Glastetter v. Novartis Pharms. Corp. (8th Cir. 2001) 252 F.3d 986, 989*. *See also Cooper v. Takeda Pharmaceuticals America, Inc. (2015), 239 Cal. App. 4th 555, 593-594*.)

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[4] Defendants argue that the use of a differential etiology methodology was not proper in the first instance because the testimony at trial was to the effect that when the causes of a disease are largely unknown (as was testified to by both Yessaian and defense experts), a differential etiology "is of little assistance." Restatement (Third) of Torts: Phys. & Emot. Harm § 28 cmt. 4 (2010); S. Breyer et. al., *Reference Manual on Scientific Evidence* 3d Ed. (2011) 618 & n. 214. The Court need not reach this issue as, even if the methodology could be used here, it was employed improperly.

The only basis upon which Yessaian opined that talc is a scientifically plausible cause of ovarian cancer was epidemiology and general reference to inflammation. But, none of the four studies on which she was permitted to rely (Cramer 1982; Rosenblatt 1992; Cramer 1999; and Wu 2009) showed odds ratios in excess of 2.0 that a woman using talc would develop serous ovarian cancer (i.e. that she had 50% or greater chance of developing cancer than women who did not use talc). Two did not break out serous ovarian cancer, although Yessaian admitted that it was important to focus on histological type (Tr. 2896:1-4; 2834:27-2835:12.) The two that did (Cramer 1999 and Wu 2009) showed a relative risk ratio of 1.70.

The other studies on which Yessaian relied to show talc was a scientifically plausible cause of serous ovarian cancer **[*49]** all showed relative risk ratios well below 2.0, i.e. in the range of 1.3. Those statistics tend to disprove causation, as they show talc does not double the risk of harm. (*Daubert v. Merrell Dow Pharm., Inc.* (9th Cir. 1995) *43 F. 3d 1311, 1321 (Emphasis in original)*; *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Prac. & Prod. Liab. Litig., (D.S.C. 2016) 185 F. Supp. 3d 786, 791-92*.) In this regard, it is to be recalled that the risk ratios being cited are *relative* risk-ratios—comparing the risk that someone who uses talc will develop ovarian cancer to the risk that someone who did not use talc will also develop cancer. A relative risk ratio of 1.3 is well below the two-fold risk level necessary to show that talc "more probably than not" causes cancer. *See Marder v. G. D. Searle (1986) 630 F. Supp. 1087, 1092*.

Further, defendants showed (and it is not disputed) that the most recent study (Cramer 2016) found the relative risk ratio for serous ovarian cancer for persons like Echeverria who were post-menopausal when they developed cancer; had not used hormone replacement therapy; and had used talc for 24 years was 1.0—i.e. no greater and no less than women in the population at large.

Echeverria argues that epidemiological studies were not required to prove causation, citing *In re Neurontin Marketing, Sales Practices, and Products Liability Litigation (D. Mass.2009) 612 F.Supp.2d 116, 132*. (Opposition at 16, FN 8.) However, the fact is that in ruling talc "in" Yessaian relied almost entirely on epidemiological **[*50]** studies. To argue that epidemiological studies are not *required* to establish causation is not persuasive given they were utilized for such purpose.

Nor is it sufficient to argue that Yessaian did not rely solely on epidemiological studies or that such studies formed only one facet of the factors she considered. (Opposition at 16:25 - 26.) Although Yessaian testified that epidemiology was just one of the factors she looked at, she did not mention any others. (Tr. 2657:25-2658:12 and 2673:10-2674:8.) She did reference prior testimony wherein she, "listed all the factors and elements that I evaluated." Presumably she was referencing testimony at Tr. 2629:20-2630:6, cited in Echeverria's Opposition at 14:28, along with a picture of the board on which Yessaian wrote her list. Within that testimony, Dr. Yessaian ruled out other causes of Echeverria's ovarian cancer, but did not find any other factor to rule in talc as a disease agent other than epidemiology.

In this regard it should be noted that Yessaian also did not "rule in" talc as a disease agent based on the testimony of Godleski or her general understanding that that there is a plausible biological mechanism (inflammation) by which **[*51]** it may be hypothesized that talc causes cancer, nor could she in the absence of evidence that Echeverria had such inflammation.

The undisputed evidence was that epidemiology was the *only* basis that Yessaian could and did "rule in" talc as a disease agent. That evidence was extremely limited and, at best, consisted of two studies (Cramer 1982 and Rosenblatt 1992) showing a relative risk ratio in excess of 2.0. In light of the other studies presented and, in particular the studies on which Yessaian relied that

showed that when stratified for serous ovarian cancer, the risk was 1.7 and for those with characteristics most closely aligned with Echeverria's (serous ovarian cancer, no use of hormone replacement therapy, and use of 24 years) no increased risk was shown, substantial evidence was not provided by Yessaian to "rule in" talc.

(ii) Yessaian Did Not "Rule Out" Other Causes of Cancer

As to what Dr. Yessaian "ruled out" in her differential etiology, Yessaian was able to testify based on Echeverria's medical and personal history that some disease agents (genetics; history of family members with cancer at an early age or breast or ovarian cancer; polycystic ovarian syndrome; endometriosis; **[*52]** tobacco and alcohol use; use of hormone replacement therapy) could be "ruled out." However, as to others (age, number of ovulatory cycles, obesity) Yessaian did not rule them out. She testified instead that in her opinion it was less probable than not that they caused Echeverria's disease. She testified that "nobody" could eliminate obesity (Tr. 2876:28-2878:12) or age (Tr. 2876:4-14), and that although a high number of ovulatory cycles was a risk factor for ovarian cancer, Echeverria's number of ovulatory cycles was "less likely than not" the cause of the disease (Tr. 2881:20-2882:23). Thus, she did not eliminate these potential causes but instead, "discounted" them. As to obesity she did so on the basis of studies showing that obesity was not statistically linked to serous ovarian cancer (although it is linked to breast and uterine cancer) but as to age and number of ovulatory cycles, her testimony had no underpinning.

Likewise, she conceded that idiopathic causes are the leading cause of ovarian cancer and that it was *probable* Echeverria's cancer was caused by some risk factor science does not yet know about (Tr. 2864:26-2688:27), yet testified that there was less than a 50% chance **[*53]** Echeverria's cancer was idiopathic. (Tr. 2888:19-26; 2890:28-2891:1; 2894:13-18.) However, she could not put a "percentage" on how less likely that was. (TR 2894: 20-21).

The Court is of the firm view that Yessaian's "ruling out" of age and ovulatory cycles, amounted to no more than speculation. Her testimony that it was "probable" the cause of the cancer was unknown, but then putting a "less than 50% chance" on same (with no reasoning) likewise amounted to mere speculation. Those facts show that the expert did not properly employ the methodology she espoused and independent of the fact that there was no evidence of substance to rule talc "in," persuade the Court that JNOV must be granted to JCCI and Johnson & Johnson on the basis that no specific causation was shown.

(2) Defendants' Arguments Regarding Scientific Knowledge

Defendants argue that there was no substantial evidence supporting a duty to warn because such duty only arises when a product is shown to be dangerous based on scientific knowledge available to the manufacturer. Echeverria argues that pursuant to *Carlin v. Superior Court (1996) 13 Cal.4th 1104, 1112-1113*, in negligent failure to warn cases there is no "generally recognized and prevailing best scientific and medical knowledge" **[*54]** requirement. This is a misreading of the case. As the *Carlin* court explained, the difference between a strict liability failure to warn and a negligence based failure to warn case is that in a strict liability setting, even a reasonably prudent defendant manufacturer (with no duty to warn under a negligence standard) may be liable if the trier of fact concludes based on scientific information available to the manufacturer, the failure to warn rendered the product unsafe. (*Id. at 1113*.) Conversely, a manufacturer who is aware of scientific evidence of a level of risk may be found to have acted within the standard of care by not warning of the risk if, for example, it had other contrary evidence. (*Id. at 1112*.) Under either

scenario, scientific knowledge is required for liability. "Under a negligence standard, a reasonable manufacturer would not be charged with knowing more than what would come to light from the prevailing scientific and medical knowledge." (*Valentine v. Baxter Healthcare Corp. (1999) 68 Cal.App.4th 1467, 1483-1484*.) However, defendants did not ask for an instruction in this regard and cannot now use that as a ground for JNOV.[5]

(3) JNOV to JJCI As To Punitive Damages Is Warranted

JJCI argues that at a minimum a partial JNOV on the issue of punitive damages should **[*55]** be granted as there was no substantial clear and convincing evidence of malice. *Cal. Civ. Code §3294(a)*. Echeverria contends that notwithstanding the fact that the scientific community was (and is) divided on the question of whether talc causes ovarian cancer, internal documents showed that JJCI "knew or should have known" that talc was dangerous or likely to be dangerous giving rise to a duty to warn and that its failure to do so was in callous disregard of the safety of the public. Specifically, she contends that JJCI was on notice that condom manufacturers ceased using talc in the early 1990s and was aware of the scientific studies both from its consultant (Weiner) and from the literature generally. At trial Echeverria argued that the literature, in particular Ex. P-105 (Harlow 1992) and Ex. P-107 (Cramer 1999) demonstrated that ten percent of ovarian cancer cases in the United States are caused by the use of talc based powders and from that fact Echeverria argued that JCCI should have warned about the risk associated with the use of talc.

This is a misreading of the evidence. Ex. P-105 was an epidemiologic study that concluded that *if* a cause association were to pertain to daily users or users with more **[*56]** than 10,000 exposures applying the odds ratios in the study to the exposure rate among cases the proportion of ovarian cancer incidence was approximately 10%. Exhibit P-107 stated that there Was a consistent association between talc and ovarian cancer that appeared to be unlikely to be explained by recall or confounding. The dose response relationship was deemed weak. The authors hypothesized a biologically plausible causation mechanism and called for appropriate warnings noting that avoidance of talc in genital hygiene use might *reduce* the occurrence of ovarian cancer by at least 10%. Other research, both before and after this, and in particular in the time period 1980 to 2008, including a published 1995 report based on a joint symposium co-sponsored by the FDA, the CFTA, and The International Association of Regulatory Toxicology & Pharmacology in January 2004 (Ex. D-205) reported that "while some weak association between talc exposure and ovarian tumors has been reported it was not sufficient warning for concern" and concluded that "the possibility of an association of talc exposure and ovarian cancer is an important hypothesis of potential public health concern. However, this association **[*57]** remains a research hypothesis whose verification or falsification needs additional study." These additional studies took place, were considered by IARC in 2006, and led it to conclude that talc was a "possible" rather than "probable" cause of ovarian cancer. (Ex. P-29; Tr. 1196:7-23; 1198:8-1200:2; 2162: 18-263: 10; 2282:5-2283: 28; 2285:23-26; 2291: 15-23.)

Significantly, Echeverria cites to no internal research or study by JCCI that was not in the public scientific domain. Thus, there was no showing beyond the publicly available literature that would show JCCI "knew or should have known" of the dangers of talc prior to 2007.

She also contends that internal documents, referenced above, showed that JCCI was attempting to influence the scientific debate at NTP, sought to influence opinion leaders, and sought to cause IARC not to list talc as "probably" carcinogenic,

[5] Defendants asked for and received an instruction as to custom and practice (*CACI 413*)

and declined to fund studies that it did not believe were favorable to it. These documents and theories are discussed, supra. The documents, beyond showing that Johnson & Johnson did not control JCCI, also do not constitute substantial evidence to support the punitive damages verdict against JCCI. The only document shown to **[*58]** have been written by a JCCI employee was P-764, the draft "Q & A". While that document demonstrates JCCI had knowledge of the science available at that time, it does not show that anyone at JCCI (much less a managing agent or employee) determined or should have determined that talc was a probable cause of cancer based on the science available.

Further, and as discussed above, that condom manufacturers ceased using talc in its products, without further information as to why they did so and that the information was known to JCCI, or that Imerys disclosed the IARC classification on its MSDS, does not show a conscious disregard for safety. Echeverria's own expert, who chaired the IARC panel giving rise to its classification of talc as "possibly" carcinogenic testified that in his opinion the scientific evidence was insufficient to show as of 2007 that there was a causal relationship between perineal talc use and ovarian cancer risk. (TR: 2300:9-14; 2300:15-19; 2362:11-22; 2355:24-2359:2; 239:3-13; 2363:10-2364:14; 2368:11-25.) The Merritt study (2008) (Ex. L-811) also concluded "chronic inflammation does not play a major role in the development of ovarian cancer."

Reviewing all of the evidence **[*59]** in the light most favorable to Echeverria the best that can be said is that there was (and is) an on-going debate in the scientific and medical community about whether talc more probably than not causes ovarian cancer and thus giving rise to a duty to warn. Clear and convincing evidence of malice is lacking. In such circumstances an award of punitive damages based on theory of negligent failure to warn of the dangers cannot be sustained. *Cf.* *Kendall Yacht Corp. v. United California Bank (1975) 50 Cal. App. 3d 949, 959*; *Satcher v Honda Motor Co. (5th Cir. 1995) 52 F. 3d 1311*.

IV. MOTION FOR NEW TRIAL

A. Procedural Requirements and Legal Standard

(1) Timeliness

A party intending to move for a new trial must file notice of intention to move for new trial designating the grounds upon which the motion is made, after a decision is rendered and before entry of judgment, or within 15 days of the date of mailing notice of entry of judgment. *CCP §659*. The Court mailed notice of entry of judgment on August 21, 2017. Defendants filed their Notice of Intention to Move for New Trial on September 5, 2017. The motion is timely.

A motion for new trial must be ruled on within 60 days of mailing of notice of entry of judgment by the clerk or any party (whichever is earlier), or if no notice is given, 60 days after filing of the first notice of **[*60]** intent to move for new trial; after such time the court loses its power to rule on a motion for new trial. Cal. Code of Civ. Pro. §663a.

The last day for the Court to rule on the motion is October 20, 2017 (60 days from August 21, 2017).

(2) Legal Standard

Courts have no inherent right to order a new trial; the right is purely statutory and must be based on one of the grounds enumerated in the statute. (*In re Marriage of Herr (2009) 174 Cal.App.4th 1463, 1465*; *Fomco, Inc. v. Joe Maggio, Inc. (1961) 55 Cal.2d 162, 166*.) The potential bases for granting a new trial are enumerated in Cal. Code of Civ. Pro. *§657*.

Defendants' motion is based on the following:

> (1) Insufficiency of the evidence to justify the verdict, or the verdict is against the law -

§657(6)

(2) Irregularity in the proceeding of the court, jury, and/or adverse party, or orders of the court or abuse of discretion by which Defendants were prevented from having a fail trial - §657(1)

(3) Error in law occurring at trial and excepted to by Defendants - §657(7).

(4) Misconduct of the jury - §657(2)

(5) Excessive damages - §657(5)

B. Analysis

(1) Cal. Code of Civ. Pro. §657(6) — Insufficiency of evidence arguments

"Insufficiency of the evidence is one of the most frequent grounds for new trial motions. It is also one as to which the trial judge has the broadest power." (Civil Trials and Evidence **[*61]** at 18:170.) The trial court is said to sit as the thirteenth juror and to have plenary power to order a new trial based on insufficiency of evidence. (*Barrese v. Murray (2011) 198 Cal.App.4th 494, 503*.) "While it is the exclusive province of the jury to find the facts, it is the duty of the trial court to see that this function is intelligently and justly performed, and in the exercise of its supervisory power over the verdict, the court, on motion for a new trial, should consider the probative-force of the evidence and satisfy itself that the evidence as a whole is sufficient to sustain the verdict." (*People v. Robarge (1953) 41 Cal.2d 628, 633 [262 P.2d 14]*.) Insufficiency of the evidence in this context means "an absence of evidence or that the evidence received, in the individual judgment of the trial judge, is lacking in probative force to establish the proposition of fact to which it is addressed." (*People v. Capps (1984) 159 Cal.App.3d 546, 552, fn. 5 [205 Cal.Rptr. 898]*.) The court must independently assess the evidence supporting the verdict. (Ibid.) The court's plenary power includes the power and duty to reweigh evidence (*Tice v. Kaiser Co. (1951) 102 Cal.App.2d 44, 46*; *Armstrong v. Svoboda (1966) 240 Cal.App.2d 472, 473)*, and to consider the credibility of witnesses and draw inferences that differ from those of the jury (*Casella v. South West Dealer Services, Inc. (2007) 157 Cal.App.4th 1127, 1159-1160)*. In reweighing evidence, trial courts are to be guided by a presumption that the verdict is correct. (*Ryan v. Crown Castle NG Networks, Inc. (2016) 6 Cal.App. 5th 775, 785*.)

Put another way, a **[*62]** trial court may uphold a jury verdict resting on sufficiently weighty evidence, even if the court itself might have reached a different conclusion. However, the trial court must conduct its own independent evaluation of the evidence, including weighing the evidence and judging the credibility of witnesses. *Id*.

In their combined Motion for New Trial, Johnson & Johnson and JJCI argue that the verdict is against the weight of evidence. They contend the evidence presented was insufficient to establish causation, and that mere possibility is insufficient to establish a prima face case. (*Jones v. Ortho Pharm. Corp. 163 Cal.App.3d at 402*.)

As to general causation, defendants argue that:

(1) The epidemiology studies do not show a strong association between genital talc use and ovarian cancer, noting that the epidemiology studies reveal average risk ratios of 1.24-1.3. (Tr. 1398:23-1402:8, 2459:5-2461:13, 3700:10-3701:8.). This relatively weak association could be the result of chance. (Tr. 1443_:12-1444:19 (Exhibit L-1769); Tr. 2332:25-2345:18; 2430:12-28; 2456:19-2458:4; 2448:14-2489:13; 3178:22-3180:20; 3361:21-3370:19; 3700:10-3705:4.)

(2) The results of studies are inconsistent. (Tr. 1426:2-15, Exhibit P-104, at 3; 1430:5-1433:5; 3714:2-3716:28; **[*63]** 1433:25-1438:5; Exhibit L-1769 Tr. 3705:9-3707:19; 3176:14-3178:7; 3361:2-20; 3721:10-3723:5; 3603:12-3607:13.)

(3) The studies fail to establish a dose-response relationship. (Tr. 3723:19-3724:1; 2389:21-2394:1; 2383:10-2389:5; 2823:3-2824:9 (L-1811); 3182:14-3183:25; 3723:8-3736:2.) Echeverria's expert, Siemiatycki, testified that although a study by Terry (2013) showed "compatibility" with dose response, it was equally compatible with no dose-response. (TR 2383:10-2389:5).

(4) No animal study has ever shown that talc causes ovarian cancer. (Tr. 3186:11-3195:20 (Hamilton 1974); 1239:23-27; 1253:26-1255:2, 3186:11-3195:20 (Ex.P-47); 1270:19-1276:28 (1995 Boorman).

(5) The proposed biological mechanism is speculative. (Tr. 3476:13-3480:23; 3492:20-26; 3464:9-3465:23; 3475:23-3480:23; 3492:20-26; 3536:4-13; 3567:12-3568:6; 3601:12-3602:1; 1359:3-10; 1363:12-19; 1383:3-9; 2483:11-2486:28; 1354:23-1357:9; Exhibit L-811; Exhibit P-47 at 3-5.)

(6) The consensus view in the regulatory, scientific, and medical community is that the science does not support a causal relationship. (Exhibit P-47; Exhibit P-29; Tr. 1196:7-23; 1198:8-12002:2; 2162:18-2163:10; 2282:5-2283:28; 2285:23-26; 2291:15-23; **[*64]** 1619:6-1620:8.) Talc is not recognized as an ovarian cancer risk by the Centers for Disease Control or medical associations such as the American Congress of Obstetrics and Gynecologists or Society of Gynecological Oncology. (Tr. 2714:2-2721:9; 3580:9-3590:5.) No published peer-reviewed articles declare talc to cause ovarian cancer. (Tr. 2276:21-2277:19; 2280:2-10; 3695:19-3696:7; 3749:12-3750:1.) The Clyde 2017 study, which was comprehensive, did not include talc as a risk factor even though it was considered as part of its analysis. (Tr. 1448:26-1459:9.)

As to specific causation, Defendants argue Yessaian's testimony was insufficient as a matter of law to prove specific causation for the reasons set forth above regarding JNOV. They further argue Yessaian's testimony was speculative and unreliable, and her credibility was undermined, because she focused only on studies that supported her conclusion while disregarding any contradictory data or cohort studies, including more recent studies, and ignored the studies she cited. They suggest "cherry-picking" metrics from different studies is not good science. (Tr. 2428:16-26; *In re Zoloft (Sertaline Hydrocloride) Prod. Liab. Litig. (E.D. Penn. 2014) 26 F.Supp.3d 449, 460-462*.). In addition, even as to the four studies on which she relied **[*65]** Yessaian used only data or metrics she considered helpful. Her report indicated she would apply data based on Echeverria's estimated 30,000 lifetime genital applications of talc (Exhibit PP at 8), which would have produced a statistically insignificant relative risk ratio under the Wu 2009 study (Tr. 2908:6-2910:28). They argue that to find a "better" odds ratio Yessaian switched to a different measure of use (years), which she had previously deemed less accurate. When questioned about this at trial Yessaian testified that the category for 50,000 lifetime applications applied to a combined genital and non-genital use, even though previously she testified that talc could not reach the ovaries through non-genital applications. (Tr. 2802:8-12.)

In contrast to Yessaian's testimony, Defendants assert their experts provided persuasive testimony that there was no inflammation in Echeveria's ovarian tissue, that most ovarian cancers are idiopathic, and that Echeverria had multiple risk factors that could account for her disease regardless of her talc use.

Echeverria asserts that sufficient evidence supporting the jury's verdict was presented, Echeverria agrees that the evidence showed that the **[*66]** relative risk ratio suggested by the bulk of the epidemiological studies was 1.3 (Tr. 2236:1-13, 3787:14-16.) She characterizes this number as statistically significant because talc is a nongenotoxic carcinogen requiring a series of mutational events to lead to ovarian cancer. (Tr. 1127:7-1128:15.) Echeverria argues based on the 6 meta-analyses and the Terry pooled analysis, plus

the consistency of the 28 epidemiology studies, it is almost impossible that association is attributable to chance or bias. (Tr. 1563:5-18, 2314:1-20, 2236:1-13, 2249:7-14, Ex. 27 (P-47).)

Echeverria's opposition also argues that as to biological plausibility, she presented evidence that inflammation is a valid hypothesis as to how talc causes cancer.

She notes that animal studies in 1992 by the NTP found lung cancer in rats exposed to high levels of aerosolized talc.

Finally, repeating arguments made in opposition to the motion for JNOV, she argues that since 1964 Defendants have been aware of "the talc/ovary problem" and yet failed to warn (Opposition at 5:13-14) or donate to cancer research (Ex P-55).

Defendants respond that Echeverria's inflammation hypothesis is not supported by studies and there was no evidence **[*67]** presented that the kind of inflammation specific to talc is linked to cancer. As to Echeverria's argument that based on meta-analysis and the Terry study, it is almost impossible that the 1.3 association is attributable to chance or bias, Defendants note that Echeverria does not dispute that the association could be based on confounding, something her own expert admits is not eliminated in meta-analysis. (Tr. 2430:12-25.)

Defendant also argues that the weight of evidence did not establish a duty to warn because such a duty is only triggered when the prevailing scientific and medical knowledge supports it. (*Valentine v. Baxter Healthcare Corp. (1999) 68 Cal.App.4th 1467, 1483-84*.)

Finally, defendants suggest the jury was likely confused by repeated suggestions that the possibility of risk alone was sufficient to impose a duty to warn. (Tr. 656:15-689:27-691:19 (mistrial requested on argument in opening statement); 3997:19-3998:4; 4005:22-27 (closing argument.)

Sitting as the thirteenth juror the Court is of the firm conclusion that the evidence of specific causation is not sufficient to support the verdict, for the reasons set forth above respecting the JNOV, which are incorporated here in their entirety, and for the additional reason that Yessaian did not **[*68]** consider all available epidemiology and apply it to the facts relative to Echeverria except when it favored Echeverria. There was a lack of any proper testimony as to specific causation. In addition, and as to general causation, the Court respects the testimony of Siemiatycki to the effect that there have been many instances in history where a disease agent was identified notwithstanding that the exact mechanism by which the disease was caused was not identified. Further, given the nature of inflammatory responses, it is understandable that inflammation may not be easily shown, as Echeverria's experts testified. However, given the lack of anything other than a hypothesis about causation and the nature of the epidemiological evidence presented, defendants are entitled to a new trial pursuant to Cal. Code of Civ. Pro. *§ 657(6)*, as both specific and general causation evidence was lacking.

(2) *CCP §657(1) (7)* - Erroneous Rulings and Improper Arguments

In order to grant a new trial based on errors in law at trial, the error must have been prejudicial (*Cal. Const. Article VI, §13*), and erroneous as a matter of law (*Tun v. Wells Fargo Dealer Services, Inc. (2016) 5 Cal.App.5th 309, 323)*. Additionally, the error must have been raised at trial. In support of their motion defendants submitted the Declarations of **[*69]** Jurors 1 and 2. Echeverria countered with the Declarations of Jurors 8 and 10.

1. Yessaian

Defendants argue that Yessaian's testimony should have been excluded or stricken because she relied on the false assumption that an odds ratio of 1.51 was sufficient to show probability. Additionally, her testimony should have been stricken when she violated the Court's order limiting it to the four

epidemiology studies as her basis for ruling in talc as the cause of Echeverria's cancer. They argue Yessaian violated that order by testifying that the four epidemiological studies were not the sole studies she relied on (Tr. 2820:11-15; 2820:1-5), but instead that she relied on other epidemiological studies with risk ratios of 1.2 to 1.3 which, in her view, showed in increase in risk that supported finding talc the probable cause of Echeverria's cancer. (Tr. 2820:26-28.) This was misleading because a risk ratio of less than 2.0 actually tends to disprove causation. Defendants moved to strike this testimony but the Court denied the motion. (Tr. 2940:1-2953:28.)

Echeverria contends these criticisms go to the weight, not admissibility of Yessaian's testimony. In addition, they argue the Court indicated **[*70]** that Yessaian was not limited to the four studies but could also testify as to Echeverria's medical history, general literature, and risk factors that she ruled out, citing the ruling on the motion in limine. Echeverria argues there was no showing of prejudice, noting that the juror declarations (which Echeverria argues should be stricken) do not say the outcome would have been different without Yessaian's testimony. Jurors 8 and 10 say they considered all the evidence and even Jurors 1 and 2 do not say the outcome would have been different without Yessaian's testimony. Finally, Echeverria points out that Defendants were free to, and did, criticize Yessaian's testimony by way of cross-examination and in closing arguments. (Tr. 4060:22-4063:7.)

Echeverria is correct that in the absence of affidavits showing prejudice, the Court may not grant a new trial under Cal. Code of Civ. Pro. §657(1). See Cal. Code of Civ. Pro §658. Accordingly, the motion for new trial on this ground is denied.

However, for the reasons set forth above the Court is persuaded that the testimony of Yessaian was insufficient to establish specific causation and should therefore have been stricken. The motion is granted on this basis **[*71]** under Cal. Code of Civ. Pro. §657(7) as to both defendants.

2. CACI 431

The Court relied upon *Cooper v. Takeda Pharmaceuticals America, Inc. (2015) 239 Cal. App. 4th 555* in instructing under *CACI 431* (multiple causation), although it indicated that it had some doubt this was appropriate. "[W]hen deciding whether an error of instructional omission was prejudicial, the court must also evaluate (1) the state of the evidence, (2) the effect of other instruction, (3) the effect of counsel's arguments, and (4) any indications by the jury itself that it was misled." (*Soule v. General Motors Corp. (1994) 8 Cal.4th 548, 580-581*.)

Defendants argue that, unlike in *Cooper*, there was no factual basis to instruct on *CACI 431* because Echeverria did not present evidence of any specific concurrent cause. Here, Yessaian did not rule in other causes while opining that talc was the most substantial factor. (Tr. 2676:1-3, 2929:21-2930:7; 2931:4-14.)

Defendants argue given the Court's rulings that Yessaian was precluded from testifying as to a possible "synergistic effect" that cause Echeverria's cancer, the fact that neither Godleski nor Yessaian testified to the biological plausibility of combined concurring causes, and the fact that defense expert Juan Felix, M.D. testified without contradiction that talc-based adhesions would not promote the growth of existing ovarian **[*72]** cancer (Tr. 3535:8-16), there was no basis for a multiple cause instruction. They contend giving the instruction likely prejudiced the results by diluting Echeverria's burden to show that talc was the "but for" cause. Defendants argue that at a critical point in deliberations, the jury discussed multiple causation (Juror #1 Declaration, ¶¶ 2-3), making it reasonably probable the jury would have reached a different result if properly instructed.

Echeverria argues that on cross-examination,

Yessaian testified to Echeverria's family history of cancer, obesity, smoking, age, age at menarche, and genetics as possible factors in causing her cancer. (Tr. 2118:18-2119:9; 2869:15-2870;27; 2875:4-10; 2876:1-14; 3597:5-15.) But, she also testified that as to each factor she determined that it was not a "probable" cause of Echeverria's cancer. It is also true, however, that defendants argued to the jury there could be other causes for Echeverria's cancer, including unknown causes.

There are no admissible juror affidavits that suggest prejudice, confusion or the like. Thus, the motion cannot be granted under Cal. Code of Civ. Pro. *§657(1)*. As to whether there was error of law the Court notes, as it did **[*73]** at trial, that in a case involving whether an agent causes cancer, where it must be shown by a more probable than not standard (in excess of 50%) that the agent caused the disease, *CACI 431* is inherently confusing because, by definition, alternate "causes" must be less than 50% probable. That is, there cannot be more than one "probable" cause in a cancer case as a mathematical matter. Nonetheless, given defendants' arguments that alternate unknown causes were possible causes of Echeverria's cancer, the Court is bound by *Cooper* and denies the motion on the basis of improper instruction under Cal. Code of Civ. Pro. *§ 657(7)*.

3. Condom Article—Ex. 19

Defendants argue that the Court improperly allowed Exhibit P-19 to be shown to the jury. The article asserts that concern about talc as an ovarian carcinogen in the medical literature goes back 50 years and that condom makers removed talc from condoms in the 1990s for that reason. Defendants argue that the Court struck Echeverria's attempt to introduce the article through Plunkett's testimony and then improperly allowed it to be introduced through defendants' expert (Andersen) even though the condom article was not part of the testimony Plunkett actually gave **[*74]** at trial and was only reviewed by Andersen as part of his consideration of Plunkett's testimony and report. (Tr. 3395:9-3396:18.) Echeverria did not ask Andersen anything about the article other than whether he had seen it. (Tr. 3397:7-22.) Although the Court gave a limiting instruction, Echeverria's counsel referred to it several times in closing argument. (Tr. 3928:10-21; 3947:21-3948:1; 3948:4-9; 3950:14-15; 3995:25-26: 4003:3-6), stating to the jury that "concern about talc as an ovarian carcinogen goes back 50 years in the medical literature" (Tr. 3947: 22-248) and arguing that the condom industry removed talc from condoms in 1996 because of ovarian cancer concerns (Tr. 3950: 14-16).

Echeverria contends there was nothing wrong with permitting cross-examination of Andersen about the article (since he said he relied on it in forming his opinion) (Tr. 3395:9-3396:18; 3396:16-22), or about allowing Echeverria's counsel to refer to it in closing arguments. Further, the Court gave a limiting instruction that it was not admissible for its truth but only for purposes of notice. (Tr. 3928:4-21.)

The Court concurs that Ex. 19 should not have been admitted and counsel's reference to it was **[*75]** both prejudicial and undermined the limiting instruction. The Supreme Court held in *People v. Sanchez (2016) 63 Cal. 4th 665* that an expert may not testify as to case specific hearsay or use same as the basis for his opinion without establishing an applicable hearsay exception. The reasoning behind the opinion was the Court's recognition, among other things, that "[w]hen an expert relies on hearsay to provide case-specific facts, considers the statements as true, and relates them to the jury as a reliable basis for the expert's opinion, it cannot logically be asserted that the hearsay content is not offered for its truth. In such a case, 'the validity of [the expert's] opinion ultimately turn[s] on the truth.'" (*Id. at 682-683*, quoting *Williams v Villinos (2012) 567 U.S. 90*). The court disapproved the use of a limiting instruction in these circumstances.

Here, the only evidence was that Andersen read the newspaper article because it was attached to

Plunkett's report and was the basis of *her* opinion. Contrary to the representation of counsel that he would "link up" the article to his cross examination of Andersen as to the basis of Andersen's opinion, he did not do so but simply read it into the record and then proceeded to argue to the jury that the facts contained within **[*76]** it were true. This resulted in a situation akin to what *Sanchez* sought to avoid—having the jury receive a fact as true through expert testimony when the fact as not been established in any reliable way. And, repeated references to it were clearly prejudicial as it was a key piece of evidence that Echeverria's counsel (Mr. Smith) relied upon in arguing that defendants knew or should have known that talc caused cancer and failed to warn of the risks in derogation of safety to the public.

Together with the other evidentiary failures a new trial on this basis is proper as to both defendants under Cal. Code of Civ. Pro. *§ 657(7)*.

4. Lobbying

Defendants argue that Echeverria's counsel disregarded limitations on use of lobbying evidence. After rejecting Echeverria's theory of conspiracy to influence regulatory agencies, (Tr. 1487:10-1488:5), the Court allowed in certain documents about attempts to influence NTP or IARC. (Ex. P-27, P-263, P-264, P-396) for the limited purpose of showing Defendant's knowledge that talc was being considered a carcinogen. (Tr. 3933:13-21.) Defense counsel objected to various lobbying exhibits and moved for a mistrial after Echeverria's counsel argued about lobbying in opening **[*77]** statement. (Tr. 691:20-693:1.)

Defendants contend Echeverria'ss counsel disregarded the limiting instruction, and this conduct was repeated and unmistakably intentional. (Tr. 3982:25-3981:1; 4094:1-8; 4094:10-14; 4090:5-11; 4093:27-28; 3989:24-3991:18; 3984:17-18; 4002:27-4003:2; 3318:20-28; 670:2-15; 3978:4-8; 4083:3-16.)

Echeverria takes the position that there was nothing improper about referring to lobbying evidence in closing argument. Echeverria argues that counsel are entitled to state their views as to what the evidence shows, citing Wegner, Civil Trials and Evidence (2017) at 13:42. Further, the Court gave a limiting instruction. (Tr. 39906:9-3908:23), while allowing the jury to consider evidence of lobbying to show knowledge of the danger of the product. (Tr. 3933:13-28; 4000:21-4001:3.)

While counsel are entitled to argue the evidence, they must do so consistent with a limiting instruction. (*Love v. Wolf (1964) 226 Cal. App. 2d 378, 389*.) Echeverria's counsel did not limit his argument to suggesting that the lobbying evidence suggested that defendants knew that there was scientific evidence concerning the possible link between talc and ovarian cancer. Rather, Echeverria's counsel (Mr. Smith) argued that defendants improperly **[*78]** "fended off" the NTP and stated that "if Johnson & Johnson would have just stayed out of it, let the scientists do their work at the U.S. government, the NTP would have listed talc as a carcinogen as far back as 2000. (TR 3982:25-3984:1.) Counsel went on to argue that what defendants did to "prevent regulation" was reprehensible conduct supporting an award of punitive damages. (TR 3984:17-18.)

Although the jury was instructed that lobbying activity was permissible, the totality of this argument disregarded the Court's limiting instruction and must be viewed as prejudicial and further grounds for a new trial as to both defendants under Cal. Code of Civ. Pro. Code of Civ. Pro. *§657(7)*.

(3) Cal. Code of Civ. Pro. *§ 657(2)* --Jury Misconduct

Defendants argue that the jury engaged in misconduct by considering attorneys' fees and taxes in its compensatory award and by setting the amount of compensatory damages based on the net worth of the defendants. Defendants offer the

declaration of Juror #1 (M.M, the foreperson) and Juror #2 (J.D.H.) Echeverria offers the affidavits of Juror #8 (P.C.) and Juror #10 (N.F.).

The three-step inquiry into jury misconduct includes (1) whether the affidavits supporting the motion **[*79]** are admissible, (2) whether the facts establish misconduct, and (3) if so, whether it was prejudicial. (*Whitlock v. Foster Wheeler, LLC (2008) 160 Cal.App.4th 149, 160*.)

Under California law juror affidavits attesting to the jury's "mental processes" are prohibited. However, consideration of "statements made" or "conduct occurring" during deliberations is permissible. (*Cal. Ev. Code § 1150*; *Krouse v. Graham (1977) 19 Cal.3d 59, 80*; *In re Stankewitz (1985) 40 Cal. 3d 391, 397-402*.)

Defendants argue that the jury engaged in two forms of misconduct.

First, the jury improperly considering attorney fees, appellate costs and taxes in determining Echeverria's noneconomic damages. (Declaration of Juror No. 1 ¶4; Declaration of Juror No. 2, ¶6.) Echeverria argues this evidence should be disregarded because it is hearsay and goes to the jury's mental process. She also argues that the conduct does not amount to misconduct in any event because Jurors 8 and 10 disagree. Finally, Echeverria argues that if there was misconduct, it was not prejudicial because Jurors 1 and 2 at most say they did not participate in the deliberations regarding damages; Defendants have not shown that absent the alleged misconduct a different result would have been reached. Defendants argue in Reply that the declarations provide clear testimony that jurors discussed and agreed to base compensatory **[*80]** damages on attorneys' fees, appellate costs, taxes, and Defendants' wealth, which establishes prejudicial misconduct.

The evidence in the jury declarations is mixed as to its admissibility. Specific rulings on the objections are appended. Briefly, however, the statements by Jurors 1 and 2 that "[Jurors] stated that taxes, appeal costs and expenses would be taken out of Ms. Echeverria's compensation" and "After jurors raised these arguments, other jurors expressed an agreement to raise the amount of damages" are admissible. The statements are proof of an overt act (an agreement to raise damages based on impermissible considerations). They are not hearsay. The statements are not admitted to show they are true (that Echeverria would pay fees and taxes) but to show the statement was made. As the Supreme Court explained in *Weathers v. Kaiser Found Hospitals*: "hearsay is defined as 'evidence of a statement that was made other than by a witness while testifying at the hearing and *that is offered to prove the truth of the matter stated*.'" (*Evid. Code, § 1200, subd. (a)*.) (Italics added.) However 'there is a well-established exception or departure from the hearsay rule applying to cases in which the very fact in controversy **[*81]** is whether certain things were said . . . and not . . . whether these things were true or false, and in these cases the words... are admissible not as hearsay, but as original evidence.'" (*Weathers v. Kaiser Found. Hosps., (1971) 5 Cal. 3d 98, 109-110*, citing *People v. Henry (1948) 86 Cal.App.2d 785, 789*. See also *Enyart v. City of Los Angeles, 76 Cal. App. 4th 499, 508, n. 5* [Statements reflecting on the bias of the jurors who uttered them are not hearsay]).

Although Echeverria secured juror declarations they did not refute what Jurors 1 and 2 reported. An agreement to exclude improper items of compensation such as taxes and fees in a verdict is improper, particularly where the jury was instructed as to what they could consider. (*Krouse, 19 Cal. 3d at 80-81*; *Trammell v. McDonnell Douglas (1984) 163 Cal. App. 3d 157, 172)*. On the evidence here the Court is constrained to conclude that consideration of items of damages such as taxes and fees was serious misconduct, giving rise to a presumption of prejudice. No rebuttable evidence was offered. A new trial on this basis is thus required as to both defendants under Cal. Code of Civ. Pro. *§ 657(2)*, particularly given that this was a 9-3 verdict. (*Weathers v. Kaiser, 5 Cal. 3d at 110*.)

Defendants also argue that the jury improperly based compensatory damages on Defendants' wealth and apportioned the damages according to net worth. The jury awarded $68 million in noneconomic damages against Johnson & Johnson as compared to the company's **[*82]** $68 billion net worth, and $2 million against JJCI as compared to its $2 billion net worth. While it may be inferred that the verdict was the result of consideration of wealth, statements regarding the manner in which the jury deliberated are inadmissible. A new trial cannot be granted on this basis.

(4) Cal. Code of Civ. Pro. *§657(5)* — Excessive Damages

(i) Compensatory Damages

Defendants argue the compensatory damage award is excessive on its face, and grossly disproportionate to the verdicts in prior talc-cancer cases and similar cases where plaintiff established that he or she was diagnosed with terminal cancer caused by defendant's product. Defendants contend this is due to improper arguments by Echeverria's counsel.

The evidence was that Echeverria was diagnosed with cancer in 2007. She underwent surgery and multiple rounds of chemotherapy, including clinical trials, and endured their side effects, for ten years. She testified that she has pain from tumors that have developed since her surgery. (Tr. 3010:1-3011:3; Tr. 2574: 26-2577: 28; 3008:22-3009:17.) She testified that she feared death when she became ill in late 2016 and was hospitalized with sepsis. (Tr. 2998:28-2999:2.) She testified **[*83]** to her fears and to the impact that her illness has had on her family, particularly her daughter, who took on the responsibility for her care at age 16 and delayed graduation from high school as a result, as well as her sadness at the potential of losing her relationship with her young grandson. (Tr. 3011: 4-19.) Yessaian testified that Echeverria had complications from the chemotherapy, resulting in multiple hospitalizations. She also testified that for a woman of Echeverria's age the average life expectancy is 81 years. (Tr. 2683:23-28.)

Given this testimony the Court is not persuaded that the compensatory damages against JCCI ($2 million) can be deemed excessive if liability were established. The number is well in line with other verdicts in comparable cases. Accordingly, as to JCCI the motion for new trial on grounds of excessive damages is denied.

As to Johnson & Johnson, however, the court is convinced that the jury should have reached a different verdict. The compensatory verdict ($68 million) is plainly excessive. As found, *infra*, there is no evidence Johnson & Johnson manufactured baby powder after 1967 and there is no evidence it manufactured Shower to Shower. Yet, the jury **[*84]** apportioned the damages 97% to Johnson & Johnson. Given the misconduct of the jury in considering matters that were not to be included, and the arguments of counsel that were in violation of the Court's in limine motions, and given the other reasons why a new trial is required, a remittitur is not appropriate. A new trial is required on the basis of excessive noneconomic damages is granted as to Johnson & Johnson under Cal. Code. of Civ. Pro. *§ 657(5)*.

(ii) Punitive Damages

Defendants argue that the punitive damage award is against the weight of evidence and excessive. Defendants contend Echeverria failed to establish by clear and convincing evidence that Defendants acted with malice. Even if allowed, Defendants contend the Court should reduce the damages as excessive and the product of passion and prejudice, driven by improper arguments seeking to punish Defendants for protected First Amendment activity and in violation of due process. *BMW of North America v. Gore (1996) 517 U.S. 559, 574-575* indicates that punitive damages are to be reviewed based on (1) the degree of reprehensibility, (2) the

disparity between the actual or potential harm suffered by the plaintiff and the punitive damage award, and (3) a comparison to civil penalties in comparable cases. Focusing **[*85]** on the second factor, Defendants cites case law showing historical practice is to compare the ratio of punitive to compensatory damages, and, although bright-line rules are to be eschewed, awards of more than four times the amount of compensatory damages, "might be close to the line of constitutional impropriety" (*State Farm Mutual Auto Ins. Co. v. Campbell (2003) 538 U.S. 408, 425)*, but where compensatory damages are substantial, a lesser ratio (1:1) can reach the due process limit. (Ibid.) Ratios of 9:1 are inherently suspect. (*Simon v. San Paolo U.S. Holding Co. (2005) 35 Cal.4th 1159, 1182*.) Echeverria points out that the 5:1 ratio here is well within the limits that have consistently been upheld but does not identify a case upholding a very significant punitive damages award layered on top of a substantial compensatory damage award.

It is sufficient to state for these purposes that the evidence was insufficient to uphold a punitive damage award of any kind. Analysis of what constitutes a "proper" amount of punitive damages is thus unnecessary. The punitive damages were excessive based on the evidence. A new trial is required as to both defendants under Cal. Code of Civ. Pro. *§ 657(5)*.

V. ORDER

For the foregoing reasons:

(1) The motions for JNOV by Johnson & Johnson and JCCI are granted;

(2) The motions for new trial by **[*86]** Johnson & Johnson and JCCI on grounds of (1) insufficiency of the evidence as to causation as to both defendants (Cal. Code of Civ. Pro. 657(6)); (2) error in law occurring at trial and excepted to by defendants (Cal. Code of Civ. Pro. 657(7); (3) misconduct of the jury (Cal. Code of Civ. Pro. 657(2); Civ. Pro. 657(2); and (4) excessive compensatory damages (as to Johnson & Johnson) and excessive punitive damages (as to both defendants)(Cal. Code of Civ. Pro. 657(5) are granted.

Dated: 10/20/17

/s/ Maren E. Nelson

MAREN E. NELSON

Judge of the Superior Court

PLEADINGS CONSIDERED

Filed September 5, 2017

- Defendant Johnson & Johnson's Notice of Intention to Move for a New Trial
- Defendant Johnson & Johnson's Notice of Motion for Judgment Notwithstanding the Verdict
- Defendant Johnson & Johnson Consumer Inc.'s Notice of Motion for Judgment Notwithstanding the Verdict

Filed September 15, 2017

- Defendants' Motion for New Trial (Combined Memorandum of Points and Authorities)
    - Defendants' Compendium of Trial Transcripts (Volumes I and II)
    - Declaration of Bart H. Williams in Support of Johnson & Johnson and Johnson & Johnson Consumer, Inc.'s Motions for New Trial and Motions for Judgment Notwithstanding **[*87]** the Verdict
        - Notice of Lodging Exhibits G and L to the Williams Declaration Conditionally Under Seal
        - Notice of Lodging Exhibits F, H, I, O, P, T, U, V, W, W and Y to the Williams Declaration Conditionally Under Seal
    - Declaration of Juror Number 1
    - Declaration of Juror Number 2

Filed September 25, 2017

• Plaintiff Eva Echeverria's Opposition to the Johnson & Johnson Defendants' Motion for New Trial
• Plaintiff Eva Echeverria's Opposition to Defendant Johnson & Johnson's Motion for Judgment Notwithstanding the Verdict
• Plaintiff Eva Echeverria's Opposition to Defendant Johnson & Johnson Consumer, Inc.'s Motion for Judgment Notwithstanding the Verdict
  ○ Declaration of Mark P. Robinson, Jr. (Under Seal and Redacted Versions)
  ○ Plaintiff Eva Echeverria's Compendium of Trial Transcript Excerpts
  ○ Evidentiary Objections to Declarations of Juror No. 1 and Juror No. 2
  ○ Request by Plaintiff and Motion to Strike Declarations of Juror Nos. 1 and 2 Submitted by Defendants
  ○ Affidavit of Juror Number 8 (P.C.)
  ○ Affidavit of Juror Number 10 (N.F.)

Filed October 3, 2017
• Defendants' Reply in Support of Motions for New Trial

  ○ Defendants' Response to Plaintiff's Request to Strike and Evidentiary Objections **[*88]** re Juror Declarations Submitted in Support of Motion for New Trial
  ○ Defendants' Objections to Plaintiff's Juror Affidavits re Defendants' Motions for New Trial
  ○ Defendants' Supplemental Compendium of Trial Transcript Excerpts
• Defendant Johnson & Johnson Consumer, Inc.'s Reply in Support of Motion for Judgment Notwithstanding the Verdict
• Defendant Johnson & Johnson's Reply in Support of Motion for Judgment Notwithstanding the Verdict

Filed October 13, 2017
• Plaintiff's Supplemental Brief re Court's Questions at Hearing on Post-Trial Motions

Filed October 16, 2017
• Defendants' response to Plaintiff's Supplemental Post-Hearing Brief

II. EVIDENTIARY OBJECTIONS TO THE DECLARATION OF JUROR NO. 1 (M.M.)

Go to table1

III. EVIDENTIARY OBJECTIONS TO THE DECLARATION OF JUROR NO. 2 (J.D.H.)

Go to table2

I. EVIDENTIARY OBJECTIONS TO THE DECLARATION OF JUROR NO. 8 (P.C.)

Go to table3

II. EVIDENTIARY OBJECTIONS TO THE DECLARATION OF JUROR NO. 10 (N.F.)

Go to table4

Exhibit C

NATURE OF PROCEEDINGS:

RULING ON SUBMITTED MATTER OF OCTOBER 12, 2017;

The Court, having taken DEFENDANTS' MOTION FOR NEW TRIAL; MOTION OF DEFENDANT JOHNSON & JOHNSON'S MOTION FOR JUDGMENT NOTWITHSTANDING VERDICT; and MOTION OF DEFENDANT JOHNSON & JOHNSON CONSUMER INC.'S MOTION FOR JUDGMENT NOTWITHSTANDING VERDICT **[*113]** under submission on October 12, 2017, issues its ruling as fully reflected in the ORDERS REGARDING

DEFENDANTS JOHNSON & JOHNSON CONSUMER, INC. AND JOHNSON & JOHNSON'S COMBINED MOTION FOR NEW TRIAL, DEFENDANT JOHNSON & JOHNSON CONSUMER INC.'S MOTION FOR JUDGMENT NOTWITHSTANDING VERDICT, AND DEFENDANT JOHNSON & JOHNSON'S MOTION FOR JUDGMENT NOTWITHSTANDING VERDICT, consisting of 70 pages, which is signed, filed, and entered in the permanent minutes of the court this date and incorporated herein as follows:

(1) The motions for JNOV by Johnson & Johnson and JCCI are granted;

(2) The motions for new trial by Johnson & Johnson and JCCI on grounds of (1) insufficiency of the evidence as to causation as to both defendants (Cal. Code of Civ. Pro. 657(6)); (2) error in law occurring at trial and excepted to by defendants (Cal. Code of Civ. Pro. 657(7); (3) misconduct of the jury (Cal. Code of Civ. Pro. 657(2); and (4) excessive compensatory damages (as to Johnson & Johnson) and excessive punitive damages (as to both defendants)(Cal. Code of Civ. Pro. 657(5) are granted.

The Clerk shall give notice by posting of this Minute Order and the ORDERS REGARDING DEFENDANTS JOHNSON & JOHNSON CONSUMER, INC. **[*114]** AND JOHNSON & JOHNSON'S COMBINED MOTION FOR NEW TRIAL, DEFENDANT JOHNSON & JOHNSON CONSUMER INC.'S MOTION FOR JUDGMENT NOTWITHSTANDING VERDICT, AND DEFENDANT JOHNSON & JOHNSON'S MOTION FOR JUDGMENT NOTWITHSTANDING VERDICT on www.CaseAnywhere.com .

CERTIFICATE OF ELECTRONIC SERVICE
CODE OF CIVIL PROCEDURE 1010.6

I, the below named Executive Officer/Clerk of the above entitled court, do hereby certify that I am not a party to the cause herein, and that on this date I served one copy of the 10/20/17 Minute Order and ORDERS REGARDING DEFENDANTS JOHNSON & JOHNSON CONSUMER, INC. AND JOHNSON & JOHNSON'S COMBINED MOTION FOR NEW TRIAL, DEFENDANT JOHNSON & JOHNSON CONSUMER INC.'S MOTION FOR JUDGMENT NOTWITHSTANDING VERDICT, AND DEFENDANT JOHNSON & JOHNSON'S MOTION FOR JUDGMENT NOTWITHSTANDING VERDICT, entered herein, 10/20/17, upon each party or counsel of record in the above entitled action, by electronically serving the document on Case Anywhere at www.CaseAnywhere.com on 10/20/17 from my place of business, Central Civil West Courthouse, 600 South Commonwealth Avenue, Los Angeles, California 90005 in accordance with standard court practices.

Dated: October 20, 2017

Exhibit D

Good cause appearing, **[*115]** on the Court's own motion and pursuant to Cal. Code of Civ. Pro. § 657, the specification of reasons contained in the Orders Regarding Defendants Johnson & Johnson Consumer, Inc. and Johnson & Johnson's Combined Motion for New Trial, Defendant Johnson & Johnson Consumer, Inc.'s Motion for Judgment Notwithstanding the Verdict, and Defendant Johnson & Johnson's Motion for Judgment Notwithstanding the Verdict, filed October 20, 2017, are modified as follows:

Page 11, line 7: Insert a comma after "Johnson & Johnson"

Page 16, line 13: Delete "products" and insert "product as"

Page 19, line 1: Delete "Emery's" and insert "Imerys'"

Page 30, line 9: Insert the following footnote: "Yessaian testified that she relied on Godleski's finding that talc was found in Echeverria's ovarian tissue. However, she did not indicate that he offered a causation opinion upon which

she relied to rule talc "in.""
Page 40, line 21.5: Insert the following after the word "causation": "(that is, how talc exposure causes ovarian cancer)"
Page 45, line 2: Delete "as" and insert "was"
Page 47, line 3.5: Delete "considering" and insert "considered"
Page 48, line 4.5: Delete "include" and insert "exclude"

There are no changes in the **[*116]** Orders.

Dated: 10/30/17

/s/ Maren E. Nelson

MAREN E. NELSON

Judge of the Superior Court

Table1 (*Return to related document text*)

Material Objected to:	Grounds for Objection:	Ruling:
"3. There were extensive *discussions* among the jurors about the distinction between 'possible' and 'probable' causes. I raised that distinction several times. **[*89]** At one point while we were *discussing* this issue, one of the jurors *raised* and pointed to the jury instruction on 'Multiple Causes,' which said in effect that there could be more than one substantial cause. After that, jurors in favor of the plaintiff *relied heavily* on that instruction in their arguments to other jurors." Juror No. 1 Decl., at ¶ 3 (italics added).	**Inadmissible pursuant to Evid. Code § 1150**. The statements in paragraph 3 of Juror No. 1's declaration concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. Such statements are inadmissible pursuant to Evid. Code § 1150 and cannot be used to try to impeach the verdict. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*; Cal. Judges Benchbook Civ. Proc. After Trial, Chp. 2, at § 2.27. "When a juror ... gives the reasons for his or her vote, the words are a verbal reflection of the juror's mental processes, and consideration of such a statement as evidence of those processes is barred by Evid. Code § 1150." *Id*.	☑ Sustained ☐ Overruled as to what the jurors relied on.
	Hearsay. Juror No. 1's statements about what other (unidentified) jurors discussed or raised verbally is inadmissible hearsay.	☐ Sustained ☑ Overruled
	Speculation. Juror No. 1's, statement about what he thinks other jurors thought was important or what they "relied heavily on" is speculation, lacks foundation and personal knowledge as to the thinking and decision-making of other jurors.	☑ Sustained ☐ Overruled
	Lacks foundation, lacks detail, [*90] and conclusory.	☐ Sustained ☑ Overruled
"4. They also *stated* that taxes, appeal costs, and expenses would be taken out of Ms. Echeverria's compensation or out of the money received by Ms. Echeverria's daughter when Ms. Echeverria passed away. After jurors *raised* those *arguments*, other jurors *expressed* an agreement to raise the	**Inadmissible pursuant to Evid. Code § 1150**. The statements in paragraph 4 of Juror No. 1's declaration concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. The statements are inadmissible pursuant to Evid. Code § 1150 and cannot be used to try to impeach the verdict. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*; Cal. Judges Benchbook Civ. Proc. After	☐ Sustained ☑ Overruled as to "They also stated... damages"

Material Objected to:	Grounds for Objection:	Ruling:
amount of the damages." Juror No. 1 Decl., at ¶ 4 (italics added).	Trial, Chp. 2, at § 2.27. "Juror declarations that purport to show a deliberative error by one or more jurors are inadmissible to impeach the verdict, as are juror declarations that purport to show . . . [h]ow the jurors arrived at the award of damages." Cal. Judges Benchbook Civ. Proc. After Trial, Chp. 2, at § 2.29 (citing Maxwell v. Powers (1994) 22 Cal.App.4th **[*91]** 1596, 1604-05).	
	Hearsay. Juror No. 1's statements about other (unidentified) jurors' "discussions," their "arguments" or what they "argued," what they "stated," what they "expressed," or "raised" verbally is inadmissible hearsay.	☐ Sustained ☑ Overruled
	Lacks foundation, lacks detail, and conclusory. Neither the substance of any such statements by others nor their identity is provided. The statements are vague and conclusory.	☐ Sustained ☑ Overruled
"5. The jury took a poll on the issue of whether defense jurors should participate in the damages discussion. After the vote, although I (as the foreperson) facilitated the damages discussion by calling on jurors on writing things on the board, I did not express my views on the amount of compensatory **[*92]** damages. The other two defense jurors did not participate in the discussion of compensatory damages after the poll was taken regarding their participation." Juror No. 1 Decl., at ¶ 5 (italics	**Inadmissible pursuant to Evid. Code § 1150**. The statements in paragraph 5 of Juror No. 1's declaration concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. Such statements' are inadmissible pursuant to Evid. Code § 1150 and cannot be used to try to impeach the verdict. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*. "No evidence is admissible to show the effect (of improper influences) upon a juror in influencing him to assent to or dissent from the verdict or concerning the mental processes by which it was determined." Evid. Code 1150(a) (emphasis added).	☑ Sustained ☑ Overruled as to "The jury... Participation
	Hearsay. Juror No. 1's statements about what one or more jurors (unidentified by name or juror number) supposedly said, discussed or expressed is	☐ Sustained ☑ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
added).	inadmissible hearsay.	
	Lacks foundation, lacks detail, and conclusory. Juror No. 1 does not have personal knowledge regarding the extent of participation of other jurors in discussions in the deliberation process.	☐ Sustained ☑ Overruled
"6. Jurors *agreed* to assess a larger amount for non-economic damages from the parent company (Johnson & Johnson) because of the ratio between the net worth of Johnson & Johnson and that of JJCI." Juror No. 1 Decl., at ¶ 6 (italics added).	**Inadmissible pursuant to Evid. Code § 1150**. The statements in paragraph 6 of Juror No. 1's declaration concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. **[*93]** These statements are inadmissible pursuant to Evid. Code § 1150 and cannot be used to try to impeach the verdict. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*; Cal. Judges Benchbook Civ. Proc. After Trial, Chp. 2,• at § 2.27. "Juror declarations that purport to show a deliberative error by one or more jurors are inadmissible to impeach the verdict, as are juror declarations that purport to show . . . [h]ow the jurors arrived at the award of damages." *Id.* at § 2.29 (citing *Maxwell v. Powers* (1994) 22 Cal.App.4th 1596, 1604-05).	☐ Sustained ☑ Overruled "Jurors agreed... JJCI"
	Hearsay. Juror No. 1's statements about what other (unidentified) jurors "discussed" or "agreed" regarding their decision-making process in awarding damages is inadmissible hearsay.	☐ Sustained ☑ Overruled
	Speculation, lacks foundation, lacks personal knowledge, conclusory. In paragraph 5, Juror No. 1 said that he and the other "defense jurors" did not participate in the damages discussion. If that was true, it would mean that he lacks foundation and personal knowledge to state why or how other jurors "agreed" to assess damages.	☐ Sustained ☑ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
"7. The jurors who voted in favor of liability *agreed* to set the number based on a percentage of the Defendants' net worth, as Allen Smith had argued in closing argument." Juror No. 1 Decl., at ¶ 7 (italics added).	**Inadmissible pursuant to Evid. Code § 1150**. The statements in paragraph 7 concern the Mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. Such statements are inadmissible. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*; Statements in "juror declarations that purport to show . . . [h]ow the jurors arrived at the award of damages" are inadmissible. Cal. Judges Benchbook Civ. Proc. After Trial, Chp. 2, § 2.29.	**[*94]** ☐ Sustained ☑ Overruled is the jurors ... agreed... argument
	Hearsay. Juror No. 1's statements about what other (unidentified) jurors "discussed" or "agreed" regarding their decision-making process in awarding damages is inadmissible hearsay.	☐ Sustained ☑ Overruled
	Speculation, lacks foundation, lacks personal knowledge. Juror No. 1. lacks personal knowledge and his statements lack foundation as to what other jurors discussed or how or why they decided or "agreed" to award damages.	☐ Sustained ☑ Overruled
	Not relevant. Evid. Code § 350. It is not misconduct to consider the defendant's **[*95]** net worth in awarding punitive damages. CACI 3945. *See also* Cal. Judges Benchbook Civ. Proc. After Trial, Chp. 2, § 2.53 ("[P]unitive damages must be supported by . . . evidence of the defendant's financial condition" and "the defendant's net worth is the critical determinant.").	☐ Sustained ☑ Overruled
"8. When the jury was at a six-to-six impasse on the Friday before the verdict, one plaintiff juror *expressed* that she no longer wanted to participate. She even turned her chair away from the table. I wrote a note to the Court about	**Inadmissible pursuant to Evid. Code § 1150**. The statements in paragraph 8 concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. The statements are inadmissible. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*. "No evidence is admissible to show the effect (of improper influences) upon a juror in	☑ Sustained ☐ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
the impasse. After we received a note back from the Court, we continued to deliberate, but the jury continued to be divided and could not **[*96]** reach the nine votes necessary to reach a verdict. The same juror *told* me that she was going to write to the judge and ask to be taken off the jury because of her frustration. She began writing a letter in front of the other jurors." Juror No. 1 Decl., at ¶ 8 (italics added).	influencing him to assent to or dissent from the verdict or concerning the mental processes by which it was determined." Evid. Code § 1150(a). **Hearsay**. Juror No. 1's statements about what some other (unidentified) juror "expressed" or "told" him or said she was going to "ask" is inadmissible hearsay. **Speculation, lacks foundation, lacks personal knowledge**. Juror No. 1's statements regarding why he thinks some other juror (who is not even identified) was frustrated is speculation and lacks foundation. **Not relevant**. *See* Evid. Code § 350: The fact that one juror at one point in time was frustrated or supposedly said that she was going to write a letter to the judge is not relevant. The statements do not show misconduct, that the juror refused to continue to deliberate or did anything improper.	☑ Sustained ☐ Overruled ☑ Sustained ☐ Overruled ☑ Sustained ☐ Overruled
"9. After the jury received the note from the Court in response to the jury note, one of the plaintiff jurors argued vociferously that the jury was being told it needed to reach a verdict. At that point, the jury took a vote using a one to ten scale to indicate how strongly we favored a given side ('1' being strongest for defense, and '10' being strongest for plaintiff). Using that methodology, the 'average' was about a '7,' even though the jury remained divided. The jury continued to	**Inadmissible pursuant to Evid. Code § 1150**. The statements in paragraph 9 are inadmissible because they concern the mental processes, deliberative thinking, **[*97]** and subjective reasoning of the jury regarding how the verdict was reached. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*. "'Evidence about a jury's 'subjective collective mental process purporting to show bow the verdict was reached' is inadmissible.'" *English v. Lin* (1994) 26 Cal.App.4th 1187, 1367. **Hearsay**. The statements about what some other jurors "argued" regarding what they were "told," and methodology referenced is hearsay. **Speculation, lacks foundation, lacks personal knowledge, lacks detail, conclusory**. Juror No. 1's statements about what he recalls the overall	☑ Sustained ☐ Overruled ☑ Sustained ☐ Overruled ☑ Sustained ☐ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
deliberate through the end of the day on Friday." Juror No. 1 Decl., at ¶ 9 (italics added).	"average" numbers referenced in the methodology being "about" for the other jurors is speculation, lack foundation, lack detail, and are vague and impermissible **[*98]** conclusions.	
	Not relevant. Jurors can consider the evidence and "express opinions regarding it." *People v. Steele* (2002) 27 Cal.4th 1230, 1266. There is nothing wrong with "jurors employ[ing] their own reasoning skills in a demonstrative manner . . . to the evidence admitted at trial." *People v. Vigil* (2011) 191 Cal.App.4th 1474, 1485.	☑ Sustained ☐ Overruled

Table1 (*Return to related document text*)

Table2 (*Return to related document text*)

Material Objected to:	Grounds for Objection:	Ruling:
"2. On Friday August 18, 2017, the jury was split 6 to 6. Our foreperson sent a note to the Judge telling her that the jury could not reach a verdict. One plaintiff juror *said* she no longer wanted to participate in discussions. She turned her chair away from the table and began writing something. After **[*99]** we received the note from the Judge and were still not able to reach a verdict, someone *said* we should just tell the Judge that we are a hung jury. At that point, one of the jurors angrily *said* that the note we received from the Judge said we had no choice but	**Inadmissible pursuant to Evid. Code § 1150**. The statements in paragraph 2 concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. Such statements are inadmissible. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*. "No evidence is admissible to show the effect (of improper influences) upon a juror in influencing him to assent to or dissent from the verdict or concerning the mental processes by which it was determined." Evid. Code § 1150(a).	☐ Sustained ☑ Overruled
	Hearsay. Juror No. 2's statements about what some other juror (unidentified by name, juror number or even gender) supposedly said or meant is inadmissible hearsay.	☐ Sustained ☐ Overruled
	Speculation, lacks foundation, lacks personal knowledge, lacks detail, and conclusory. Juror No. 2's statements are vague, lack foundation, are	☐ Sustained ☑ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
to reach a verdict." Juror No. 2 Decl., at ¶ 2 (italics added).	speculative, conclusory and lack sufficient detail. **Not relevant**. *See* Evid. Code § 350. The fact that one juror at one point in time may have been frustrated or supposedly said that she was going to write a letter to the judge is not relevant. The statements do not show misconduct, that deliberations did not continue, or anyone did anything improper.	☑ Sustained ☐ Overruled
"3. We were not able to reach a verdict on Friday August 18. My best memory is that the jury was still divided 7 to 5 in favor of the plaintiff at the end of the day." Juror No. 2 Decl., at ¶ 3.	**Inadmissible pursuant to Evid. Code § 1150**. The **[*100]** statements in paragraph 3 concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. The statements are inadmissible. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*. "No evidence is admissible to show the effect (of improper influences) upon a juror in influencing him to assent to or dissent from the verdict or concerning the mental processes by which it was determined." Evid. Code § 1150(a). "Evidence Code 1150 may be violated not only by the admission of jurors' testimony describing their own mental processes, but also by permitting testimony concerning statements made by jurors in the course of their deliberations." *People v. Sanchez* (1998) 62 Cal.App.4th 460, 475-76. "[T]he mental processes of jurors are beyond the hindsight probing of the trial court." *Maple v. Cincinatti, Inc.* (1985) 163. Cal.App.3d 387, 394. The rule prevents one or two jurors "from upsetting a verdict of the whole jury by impugning his own or his fellow jurors' mental process or reasons for assent or dissent." Wegner, at **[*101]** ¶ 18:288.	☐ Sustained ☑ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
4. "On Monday August 21, 2017, two more jurors switched to the plaintiff side, giving the plaintiff 9 votes." Juror No. 2 Decl., at ¶ 4.	Inadmissible pursuant to Evid. Code § 1150. The statements in paragraph 4 concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. Such statements are inadmissible. Evid. Code § 1150(a); *see also* § I.A. *supra*. "No evidence is admissible to show the effect (of improper influences) upon a juror in influencing him to assent to or dissent from the verdict or concerning the mental processes by which it was determined." Evid. Code § 1150(a). "'Evidence about a jury's 'subjective collective mental process purporting to show how the verdict was reached' is inadmissible to impeach a jury verdict.'" *English v. Lin* (1994) 26 Cal.App.4th 1187, 1367. "[T]he mental processes of jurors" is not admissible. *Maple v. Cincinatti, Inc*. (1985) 163 Cal.App.3d 387, 394.	☐ Sustained ☑ Overruled
	Speculation, lacks foundation, lacks detail and conclusory. Juror No. 2 lacks personal knowledge and her statements lack foundation as to the reasons and decision making process of the other jurors — after "almost no **[*102]** discussion" — whatever that means, and what they considered or deemed important in reaching their verdict. She does not say which jurors "switched" and she does not say or know why.	☐ Sustained ☑ Overruled
"5. Once the *discussion* of one of the jurors who favored the plaintiff angrily *said* that those of us who had favored the defense should not participate in the discussion of damages. A	**Inadmissible pursuant to Evid. Code § 1150**. The statements in paragraph 5 of Juror No. 2's declaration concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. Such are inadmissible statements pursuant to Evid. Code §	☐ Sustained ☑ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
vote was taken regarding whether we should be allowed to participate in the discussion of damages. After the majority of jurors voted that we should not participate, the three of us who had voted for the defense did not participate in the discussion of how to decide on an amount for compensatory damages, or on the amount of damages." Juror No. 2 Decl., at ¶ 5 (italics added).	1150 and cannot be used to try to impeach the verdict. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*. "No evidence is admissible to show the effect (of improper influences) upon a juror in influencing him to assent to or dissent from the verdict or concerning the mental processes by which it was determined." Evid. Code 1150(a) (emphasis added). **[*103]** The rule prevents one or two jurors "from upsetting a verdict of the whole jury by impugning his own or his fellow jurors' mental process or reasons for assent or dissent." Wegner, at ¶ 18:288.	
	Hearsay. Juror No. 2's statements about what one of jurors (unidentified by name or juror number) supposedly said, discussed or expressed is inadmissible hearsay.	☐ Sustained ☑ Overruled
	Lacks foundation, lacks detail, and conclusory. Juror No. 2 does not have personal knowledge and her vague statements lack foundation regarding the extent of participation of other jurors in discussions in the deliberation process.	☐ Sustained ☑ Overruled
"6. The jurors who favored the plaintiff *said* they should increase the amount of damages that they had been *discussing* because Ms. Echeverria was going to have to pay taxes **[*104]** on the money, pay her lawyers, and pay for an appeal. After the jurors *raised* those possible costs, other jurors agreed to raise the amount of the damages.	**Inadmissible pursuant to Evid. Code § 1150**. The statements in paragraph 6 of Juror No. 2's declaration concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. Such statements are inadmissible pursuant to Evid. Code § 1150 and cannot be used to try to impeach the verdict. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*; Cal. Judges Benchbook Civ. Proc. After Trial, Chp. 2, at § 2.27. "Juror declarations that purport to show a deliberative error by one or more	☐ Sustained ☑ Overruled in part

Material Objected to:	Grounds for Objection:	Ruling:
Juror No. 2 Decl., at ¶ 6 (italics added).	jurors are inadmissible to impeach the verdict, as are juror declarations that purport to show . . . [h]ow the jurors arrived at the award of damages." *Id.* at §2.29.	
	Hearsay. Juror No. 2's statements about what other (unidentified) jurors "said," were "discussing," or verbally "raised" or "agreed" regarding their decision-making process in awarding damages is inadmissible hearsay.	☐ Sustained ☑ Overruled
	Speculation, lacks foundation, lacks personal knowledge, conclusory. In paragraph 5, Juror No. 2 said that she and the other "defense jurors" did not participate in the damages discussion. If that was true, it would mean that she has no basis to say why or how other jurors "decided" or "agreed" to assess damages.	☐ Sustained ☑ Overruled
"7. When the **[*105]** jury *discussed* the amount of punitive damages, the jurors who voted in favor of liability did what Allen Smith asked them to do in his closing argument — they set the number based on a percentage of the Defendants' net worth."	**Inadmissible pursuant to Evid. Code § 1150**. The statements in paragraph 7 concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. Such statements are inadmissible. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*; Statements in "juror declarations that purport to show . . . [h]ow the jurors arrived at the award of damages" are inadmissible. Cal. Judges Benchbook Civ. Proc. After Trial, Chp. 2, § 2.29.	☑ Sustained ☐ Overruled
	Hearsay. Juror No. 2's statements about what other (unidentified) jurors said or their decision-making process in calculating damages based on what Juror No. 2 heard them say is hearsay.	☐ Sustained ☑ Overruled
	Speculation, lacks foundation, lacks personal knowledge. Juror No. 2 lacks personal knowledge and her statements lack foundation as to what other jurors discussed or how or why they decided or	☑ Sustained ☐ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
	"set" to award damages.	
	Not relevant. Evid. Code § 350. It is not misconduct **[*106]** to consider the defendant's net worth in awarding punitive damages. CACI 3945. *See also* Cal. Judges Benchbook Civ. Proc. After Trial, Chp. 2, § 2.53 ("[P]unitive damages must be supported by . . . evidence of the defendant's financial condition" and "the defendant's net worth is the critical determinant.").	☐ Sustained ☑ Overruled

Table2 (*Return to related document text*)

Table3 (*Return to related document text*)

Material Objected to:	Grounds for Objection:	Ruling:
¶ 4, lines 10-11: "[E]veryone in the jury room was free to participate in the damages deliberations . . . ."	**Vague and ambiguous**. The phrase "everyone in the jury room was free to participate in the damages deliberations" appears intended to address the contention in defense jurors' declarations that they were directed not to deliberate on damages, without actually refuting it. Two sentences later in the juror's declaration, she professes being unable to remember "whether or not" defense jurors were requested not to participate in damages deliberations. The two contentions—that defense jurors were requested not to deliberate on damages and that they were nonetheless "free to participate in the damages deliberations"—are not necessarily mutually exclusive, where being **[*107]** "free to participate" means something short of having a vote on the final awarded amount. *See* Evid. Code §§ 352, 765.	☑ Sustained ☐ Overruled
	Evidence Code § 1150 (Improper Statement of Jurors' Subjective Reasoning/Mental Process). While testimony that specific jurors were told not to participate in damages	☑ Sustained ☐ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
	deliberations, or did or did not in fact participate in them, could be admissible as observable conduct, this juror's subjective opinion about whether defense-leaning jurors were "free to participate in the damages deliberations" is an improper statement of mental processes to the extent it is based on the juror's vague feeling or sense of the room, rather than on actual statements made.	
¶ 4, lines 12-13: "Everyone was given a chance to say what they thought about the amount to award Ms. Echeverria, including the jurors who voted for the defendants."	**Vague and ambiguous** as to the phrase "[e]veryone was given a chance to say what they thought." That language appears to be a lawerly non-refutation of the contention in defense jurors' declarations that they were directed not to deliberate on damages. Indeed, the very next sentence of the juror's declaration states that she cannot remember "whether **[*108]** or not" defense jurors were asked not to participate in damages deliberations. The two contentions—that defense jurors were requested not to deliberate on damages and that, notwithstanding, they could have interposed "what they thought about the amount"—are not necessarily mutually exclusive, where having "a chance to say what they thought" means something short of being permitted to vote. *See* Evid. Code §§ 352, 765.	☑ Sustained ☐ Overruled
	Evidence Code § 1150 (Improper Statement of Jurors' Subjective Reasoning/Mental Process). While testimony that specific jurors were told not to participate in damages deliberations, or did or did not in fact participate in them, could be admissible as observable conduct, this juror's subjective opinion about whether "[e]veryone was given a chance to say what they thought" is an	☑ Sustained ☐ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
	improper statement of, mental processes to the extent it is based on a vague feeling rather than on actual statements made in the jury room.	
¶ 4, lines 13-15: "I do not remember a request to exclude jurors from these deliberations, but whether **[*109]** or not that happened; everyone on the jury participated in reaching the verdict, and no one was excluded."	**Vague and ambiguous** as to the phrase "everyone on the jury participated in reaching the verdict, and no one was excluded." That artfully worded phrase appears calculated to distinguish between the finding of liability and the damages the jury ultimately awarded. It cannot be true both that there was a "request to exclude jurors from these deliberations" (about which, the juror avers, she cannot remember "whether or not that happened") and that "everyone on the jury participated in reaching the verdict, and no one was excluded" if "verdict" includes deliberations respecting damages. *See* Evid. Code §§352, 765.	☑ Sustained ☐ Overruled
¶ 5, lines 16-17: "Along with the other jurors, I voted based on the evidence that was presented against each of the defendants and the law that we were instructed to follow."	**Evidence Code § 1150** (Improper Statement of Jurors' Subjective Reasoning/Mental Process). The statement as to what this juror purports to have subjectively considered in voting is inadmissible both as it concerns her own vote and particularly as it concerns the votes of other jurors. The statement goes to the subjective reasoning of the jury in reaching its verdict and is not verifiable and/or based on observable facts/expressions. **Conclusory, and lacks foundation [*110] and personal knowledge** as to the basis for other jurors' votes. *See* Evid. Code § 702.	☑ Sustained ☐ Overruled
¶ 6, lines 22-23: "The evidence presented was considered and was interpreted by me based on my thinking about the	**Evidence Code § 1150** (Improper Statement of Jurors' Subjective Reasoning/Mental Process). The statement as to how this juror purports to have interpreted the evidence and	☑ Sustained ☐ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
evidence."	her subjective "thinking" is an example of her subjective reasoning, not verifiable and/or based on observable facts/expressions.	
¶ 6, lines 23-24: "We all worked together and we used our own reasoning skills in a demonstrative manner based on the evidence that was presented in the trial."	**Evidence Code § 1150** (Improper Statement of Jurors' Subjective Reasoning/Mental Process). The statement as to how this juror perceives the collective reasoning skills of the jury (and each juror individually, including herself) is not verifiable and/or based on observable facts/expressions.	☑ Sustained ☐ Overruled
	Conclusory, and lacks foundation and personal knowledge as to the basis for the other jurors' deliberations and the manner in which they reached a verdict. *See* Evid. Code § 702.	☑ Sustained ☐ Overruled
	Vague and ambiguous as to the phrase **[*111]** "demonstrative manner," which appears to have been inserted merely in order to avoid the prohibition of Evidence Code § 1150 on juror declarations concerning "mental processes." *See* Evid. Code §§ 352, 765.	☑ Sustained ☐ Overruled

Table3 (*Return to related document text*)

Table4 (*Return to related document text*)

Material Objected to:	Ground for Objection:	Ruling:
¶ 3, line 10: "The compensatory damages verdict was a reasonable compromise."	**Evidence Code § 1150** (Improper Statement of Jurors' Subjective Reasoning/Mental Process). Whether the juror believes the damages verdict was a "reasonable compromise" is not verifiable and/or based on observable facts/expressions.	☑ Sustained ☐ Overruled
	Conclusory and lacks foundation as to whether the verdict was "a reasonable compromise." *See* Evid. Code § 702.	☑ Sustained ☐ Overruled
¶ 3, line 11: "Even though I wanted to award her more, I agreed to the lower amount."	**Evidence Code § 1150** (Improper Statement of Jurors' Subjective Reasoning/Mental Process). Whether the juror wanted to award any more or less	☑ Sustained ☐ Overruled

Material Objected to:	Ground for Objection:	Ruling:
	is not verifiable and/or based on observable facts/expressions."	
¶ 3, lines 20-21: "From my standpoint, I am proud of the fact that all of us were very conscientious in a way that we considered all of the evidence that was presented."	**Evidence Code § 1150** (Improper Statement of Jurors' **[*112]** Subjective Reasoning/Mental Process). The juror's statement about what "all of us [the jury]" "considered" goes to her subjective reasoning and is not verifiable and/or based on observable facts/expressions.	☑ Sustained ☐ Overruled
	Conclusory, and lacks foundation and personal knowledge as to whether the other jurors were conscientious or considered all of the evidence. *See* Evid. Code § 702.	☑ Sustained ☐ Overruled
¶ 3, lines 22-23: "I believe that the process was fair to both the plaintiff and the defendants."	**Evidence Code § 1150** (Improper Statement of Jurors' Subjective Reasoning/Mental Process). The juror's statement of belief as to the fairness of "the process" goes to her subjective beliefs/reasoning and is not verifiable and/or based on observable facts/expressions.	☑ Sustained ☐ Overruled

Table4 (*Return to related document text*)

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EXHIBIT C

Carl v. Johnson & Johnson

Superior Court of New Jersey, Law Division, Atlantic County

September 2, 2016, Decided; September 2, 2016, Filed

DOCKET No.: ATL-L-6546-14, CIVIL ACTION NO.: 300 (MCL), DOCKET No.: ATL-L-6540-14

Reporter
2016 N.J. Super. Unpub. LEXIS 2102 *

BRANDI CARL, PLAINTIFF v. JOHNSON & JOHNSON, ET AL., DEFENDANT;DIANA BALDERRAMA, PLAINTIFF v. JOHNSON & JOHNSON, ET AL., DEFENDANT

Notice: NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS.

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Counsel: **[*1]** RICHARD GOLOMB, ESQUIRE, PLAINTIFF.

RUBEN HONIK ESQUIRE, PLAINTIFF.

PAUL R. D'AMATO, ESQUIRE, PLAINTIFF.

TED G. MEADOWS, ESQUIRE, PLAINTIFF.

DAVID B. DEARING, ESQUIRE, PLAINTIFF.

TIMOTHY W. PORTER, ESQUIRE, PLAINTIFF.

MICHELLE PARFITT, ESQUIRE, PLAINTIFF.

GENE M. WILLIAMS, ESQUIRE, DEFENDANT.

SUSAN M. SHARKO, ESQUIRE, DEFENDANT.

JULIE TERSIGNI, ESQUIRE, DEFENDANT.

MICHAEL R. KLATT, ESQUIRE, DEFENDANT.

LORNA DOTRO, ESQUIRE, DEFENDANT.

HUNTER K. AHERN, ESQUIRE, DEFENDANT.

KENNETH J. FERGUSON, ESQUIRE, DEFENDANT.

MARK C. HEGARTY, ESQUIRE, DEFENDANT.

ANN THORTON FIELD, ESQUIRE, DEFENDANT.

Judges: NELSON C. JOHNSON, J.S.C.

Opinion by: NELSON C. JOHNSON

Opinion

TALC-BASED POWDER PRODUCTS LITIGATION

NELSON C. JOHNSON, J.S.C.

HAVING CAREFULLY REVIEWED THE MOVING PAPERS AND RESPONSES FILED, I HAVE RULED ON THE ABOVE CAPTIONED MATTERS AS FOLLOWS:

I. POSTURE OF ISSUES BEFORE THE COURT

This matter is before the court on the motion of the Defendants, Johnson & Johnson and Imerys Talc America, Inc. (hereinafter referred to collectively as "Defendants") seeking relief against Brandi Carl and Diana Balderrama (hereinafter the "Plaintiffs"), both of whom brought claims alleging that a talc-based product manufactured by Defendants has caused each of **[*2]** them to develop ovarian cancer.

These two lawsuits were filed in the Superior Court of New Jersey, Atlantic County; the *Carl* matter on November 17, 2014 and the *Balderamma* matter on November 25, 2014. Pursuant to *R. 4:38A*, on October 20, 2015, the Supreme Court designated this litigation as a Multi-County Litigation (MCL), to receive centralized management by this court. The court is confident that, in these matters, every

avenue of legal and scientific research has been explored by capable legal counsel and learned scientists, and that the litigants' interests have been well represented.

Presently before the court is a challenge brought by Defendants to Plaintiffs' contention that the use of talc-based products caused them to develop ovarian cancer; said challenge was brought by motions to bar testimony of each of Plaintiffs' several expert witnesses. [NOTE: Defendants have filed companion motion(s) for summary judgment seeking dismissal of Plaintiffs' Complaints in the event the motion(s) to bar testimony are granted.] Defendants' challenge to Plaintiffs' experts was heard, and expert testimony, together with legal briefs and oral argument of counsel, were received by the court at a plenary **[*3]** hearing conducted pursuant to the standards articulated by the Supreme Court in *Kemp v. State of New Jersey, 174 N.J. 412, 809 A.2d 77 (2002)*, (hereinafter a "*Kemp* Hearing") as required by *Evid R. 104* and consistent with *Evid. R. 702*. The court conducted said hearing on August 8, 9, 11, 12, 15, 16, and 19, 2016.

Defendants argue that Plaintiffs' hypotheses as to both general and specific causation are flawed; that there is no reliable scientific evidence to support Plaintiffs' contentions; and that accordingly, Plaintiffs' experts must be barred from testifying at trial. In reply, Plaintiffs argue that their experts are qualified by education, training, and experience and that their opinions are reliable because they are based on a sound scientific methodology, involving the type of information relied upon by experts in their field.

Thus, in evaluating the totality of the evidence presented by Plaintiffs, the question before the court may be stated as follows: Have Plaintiffs shown that their experts' theories of causation are sufficiently reliable as being based on a sound, adequately-founded scientific methodology, *to wit*, that they are based upon methods upon which experts in their field would reasonably rely in forming their own (possibly different) opinions about **[*4]** the cause(s) of each of Plaintiffs' ovarian cancers?

Courts are experts in the law, not science. This court's review "is as broad as the breadth of the proffer and the challenges thereto that the parties present." *Hisenaj v. Kuehner, 194 N.J. 6, 19, 942 A.2d 769 (2008)*. Accordingly, this court's role is that of a "gatekeeper" who — based upon the proofs presented by the parties - must assess whether or not the hypotheses of causation advanced by Plaintiffs' experts are sufficiently reliable to be presented to a jury.

II. SCIENTIFIC STUDIES

Prior to receipt of testimony from the parties' experts, the court solicited from counsel the submission of all reports, abstracts, epidemiology studies, and peer-reviewed articles ("treatises" or "scientific literature") that were relied upon by the witnesses in formulating their opinions. That process began several months prior to the *Kemp* Hearing. As a result, approximately 100 treatises relating to talc, cancer, and miscellaneous related scientific issues were reviewed by the court both prior to and during the hearing. The court is grateful to counsel for these submissions; they were invaluable in preparing for the hearing and analyzing the evidence presented. [NOTE: Accompanying this ruling are Appendices **[*5]** A thru E which catalogue a portion of the peer-reviewed articles discussed at the hearing, together with public pronouncements by agencies possessing authoritative knowledge on cancer.]

Of particular value to the court in making its analysis is *The Reference Manual on Scientific Evidence* (3rd Edition, hereinafter, "the *Reference Manual*") issued by the Federal Judicial Center and the National Research Council of the National Academies. The *Reference Manual* is an invaluable tool. Because it is indicative of what the scientific community deems to be reasonable, the *Reference Manual* provides excellent guidance to trial judges in sifting through and prioritizing the information generated at a *Kemp* Hearing. At such a hearing, a

court is asked to assess whether the experts in the field would reasonably rely on methods and data as Plaintiffs' experts have done in this case. Through the *Reference Manual*, the scientific community "speaks" to trial courts, and advises as to what may be considered to be reasonable, from an informed and objective perspective.

III. INITIAL FINDINGS RE: EXPERT WITNESSES

Based upon consideration of the experts' written submissions and a careful review of all witnesses' **[*6]** testimony, together with the court's reading of the learned scientific treatises referenced herein, the court makes the following findings:

A. *Expert Witnesses*

The vine witnesses who testified at the *Kemp* Hearing are exceptionally learned and accomplished professionals; their credentials are impressive. No serious challenge was made to the qualifications of any witness. The court benefited greatly from their testimony. A brief profile of each witness follows:

Witnesses for Plaintiffs

(1) *Graham A. Colditz, M.D., MPH, DRPH, FAFPHM*: Dr. Colditz trained in Medicine at the University of Queensland, obtaining a M.B., B.S. degree. He trained in Epidemiology at Harvard School of Public Health, obtaining a Master of Public Health degree and subsequently a Doctorate. Dr. Colditz is the Niess-Gain Professor of Medicine at Washington University School of Medicine and the Associate Director, Prevention & Control, at the Alvin J. Siteman Cancer Center. He is the Chief of the Division of Public Health and Sciences in the Department of Surgery at Washington University School of Medicine. Dr. Colditz also serves as co-director of the Biostatistics Core for the Siteman Cancer Center. Dr. Colditz was presented **[*7]** on the issue of general causation of ovarian cancer.

(2) *Daniel W. Cramer, M.D., Sc.D.*: Dr. Cramer received his M.D. degree from the University of Colorado School of Medicine and a Doctor of Science degree in Epidemiology from the Harvard School of Public Health. Dr. Cramer is a Professor of Obstetrics, Gynecology and Reproductive Biology at Brigham and Women's Hospital, Harvard Medical School, and Professor of Epidemiology at the Harvard T.H. Chan School of Public Health. He heads the Research Division of the OB-GYN Epidemiology Center, doing research in the field of environmental and genetic risk factors for a variety of obstetrical and gynecologic problems with a particular focus on ovarian cancer. Dr. Cramer was presented on the issues of both general and specific causation of ovarian cancer.

(3) *John J. Godleski, M.D.*: Dr. Godleski received his M.D. degree from the University of Pittsburgh School of Medicine. He is a Professor of Pathology at Harvard Medical School, Brigham and Women's Hospital, and a Professor of Environmental Health at Harvard TH Chan School of Public Health. Dr. Godleski has published more than 160 papers related to pulmonary/environmental pathology including **[*8]** a number using analytical electron microscopy. He currently leads the Particles Research Core in the Harvard-NIEHS Environmental Research Center and serves as Associate Director of the Harvard Clean Air Research Center supported by the US Environmental Protection Agency. Dr. Godleski was presented on the identification of particles, and on the issue of specific causation of ovarian cancer.

(4) *Curtis J. Omiencinski, Ph.D., ATS*: Dr. Omiencinski is an elected fellow and professor in the Academy of Toxicological Sciences and a Professor and the H. Thomas and Dorothy Willits Hallowell Chair in the Center for Molecular Toxicology & Carcinogenesis and the Department of Veterinary and Biomedical Sciences, College of Agricultural Sciences, at The Pennsylvania State University. He received his B.S. degree from the State University of New York at Albany and his Ph.D. degree in Pharmacology from the University of Washington's School of Medicine. He has

authored more than 115 peer-reviewed papers and has published over 30 reviews, book chapters and other reports in the areas of pharmacology, molecular biology, toxicology, cancer research and genetics. His testimony was presented in connection with **[*9]** Plaintiffs' hypothesis of biologic causation of ovarian cancer.

(5) *David C. Steinberg, MBA, FRAPS*: Mr. Steinberg owns a regulatory consulting firm for the cosmetic industry, specializing in the chemistry of cosmetic ingredients, preservatives and preservation, international and U.S. cosmetic regulations, and marketing of raw materials. He received his B.S. degree in Chemistry from Drexel University and an MBA Management degree from Pace University. He is a Fellow for the Regulatory Affairs Professionals Society.

Witnesses for Defendants

(1) *Lewis A. Chodosh, M.D., Ph.D.*: Dr. Chodosh is a physician and cancer researcher. He graduated *summa cum laude*, Phi Beta Kappa from Yale University with Distinction in Molecular Biophysics and Biochemistry. He received his M.D. degree from Harvard Medical School, graduating *magna cum laude* and his Ph.D. degree in Biochemistry from the Massachusetts Institute of Technology. Dr. Chodosh currently serves as Chairman of the Department of Cancer Biology and is a Professor in the Department of Cancer Biology and in the Department of Medicine in the Division of Endocrinology, Diabetes and Metabolism at the University of Pennsylvania School of Medicine. He **[*10]** also serves as Associate Director for Basic Science in the Abramson Cancer Center at the University of Pennsylvania, as well as the Director of Cancer Genetics at the Abramson Family Cancer Research Institute. Dr, Chodosh testified as to the diverse means by which cancer(s) develop in the human body and challenged the fundamental bases of Plaintiffs' biological hypothesis and contentions regarding specific causation.

(2) *Mary J. Cunningham, M.D.*: Dr. Cunningham is a board-certified gynecologic oncologist with GynOncology of Central New York in Syracuse, New York. She received her M.D. degree from Northwestern University Medical School. Dr. Cunningham serves as a Professor in the Department of Obstetrics and Gynecology and Director of the Division of Gynecologic Oncology at the State University of New York Upstate Medical University. She is a member of the American Congress of Obstetricians and Gynecologists and the Society of Gynecologic Oncology and the Principal Investigator for with the NRG Oncology cooperative trial group. Dr. Cunningham was presented in opposition to the testimony of Dr. Colditz and Dr. Cramer.

(3) *Elaine F. Schumacher*: Ms. Schumacher is a Senior Research Scientist **[*11]** and Analytical Microscopist with McCrone Associates, Inc. of Westmont, Illinois. She received her B.S. degree in Chemistry from Elmhurst College. Ms. Schumacher is a member of Microscopy Society of America, Midwest Microscopy and Microanalysis Society, Microanalysis Society and American Chemical Society. In addition, she has authored several publications on the application of microscopy. Ms. Schumacher was presented in opposition to the testimony of Dr. Godleski.

(4) *Douglas L. Weed, M.D., M.P.H., Ph.D.*: Dr. Weed serves as a member of the Ethics Committee of the American College of Epidemiology. He received his B.S. and M.D. degrees from Ohio State University and his Ph.D. and M.P.H in Epidemiology degree from the University of North Carolina at Chapel Hill. Dr. Weed has 25 years of service at the National Cancer Institute ("NCI") and serves as a Visiting Professor at numerous universities. He is the Review Editor of the Journal of the NCI and a peer reviewer for many medical journals in the field of epidemiology. Dr. Weed has authored more than 30 peer-reviewed papers on causation methodology and systematic reviews, as well as meta-analyses of cancer epidemiology studies. Dr. Weed **[*12]** was presented in

opposition to the testimony of Dr. Colditz and Dr. Cramer.

IV. CASE LAW PERTINENT TO THE COURT'S ANALYSIS

As confirmed by the case law cited hereinafter, New Jersey's courts recognize that litigants claiming that they were harmed by the use of a product may never recover if they must await general acceptance by the scientific community of a reasonable, but not as yet certain, theory of causation linking the harm claimed to the product ingested. Because of our courts' concern that — despite compelling indicators linking a product to the harm — plaintiffs may never recover for their injuries, there are situations in which a theory of causation that has not yet reached general acceptance in the scientific community may still be found sufficiently reliable to support submission of such a claim to a jury.

In his learned essay first published in the *New Jersey Law Journal* on May 5th and 12th of 1988 (*see* 121 *N.J.L.J.* Index Page 882, *et seq.*), Justice Handler noted that "...there are many new classes of litigation, such as those involving exposure to toxic contaminants, asbestos and carcinogens, that pose complicated and novel problems." Justice Handler noted the "warfare" in **[*13]** our courtrooms is oftentimes resolved by the testimony of experts from diverse fields of knowledge:

> The point is that there is no difference in the treatment of testimony of social scientists and psychologists, on the one hand, and chemists or biologists, on the other. Differences in acceptability have more to do with expanding frontiers of scientific knowledge.
>
> 121 *N.J.L.J* Index at 883.

Until the final decade of the 20th Century, the time-honored test for the admissibility of expert testimony based upon a body of knowledge peculiar to a field of scientific study was that it had to be generally accepted or had been accepted by at least a substantial minority of the scientific community. *See* *Frye v. United States, 293 F. 1013, 54 App. D.C. 46 (D.C. Cir. 1923)*. In *Rubanick v. Witco Chem. Corp., 125 N.J. 421, 432, 593 A.2d 733 (1991)*, our Supreme Court modified that test with regard to evidence proffered for use in toxic tort cases. The Court held that a less stringent test than the general acceptance test should apply with regard to "new or developing theories of causation in toxic-tort litigation." *Id. at 432*. In writing for the Court, Justice Handler spoke of a methodology based test, that is, if the methodology by which the expert reached a conclusion is sound, the conclusion may be introduced into evidence. *Id. at 438-40*.

Pursuant to *Rubanick*, the key to reliability **[*14]** is the determination that the expert's opinion is based on a "sound, adequately-founded scientific methodology involving data and information of the type reasonably relied on by experts in the scientific field." *Id. at 449*. In order to be *valid methodology* (*viz.*, accepted by others in the scientific community), the expert's opinions must be supported by "prolonged, controlled, consistent, and validated experience." *Id. at 436*.

As this court understands *Rubanick* in determining whether a scientific methodology is valid, trial courts must consider whether other scientists in the field use similar methodologies in forming their opinions and also should consider other factors that are normally relied upon by medical professionals. The appropriate inquiry is not whether the court thinks that the expert's reliance on the underlying data was reasonable, but rather whether comparable experts in the field would actually rely on that information. With regard to evaluating the testimony of knowledgeable experts in order to determine the acceptability of a theory, the *Rubanick* Court cautioned trial courts to attend to "the hired gun phenomenon," *i.e.*, that an expert can be found to testify to the truth of almost any **[*15]** factual theory or to disagree with almost any theory and to discount the research of others. *Rubanick, supra at 453* (citations omitted).

Following *Rubanick*, in *Landrigan v. Celotex Corp., 127 N.J. 404, 605 A.2d 1079 (1992)*, *Caterinicchio v. Pittsburgh Corning Corp., 127 N.J. 428, 605 A.2d 1092 (1992)*, and *Dafler v. Raymark Industries, Inc., 259 N.J. Super. 17, 36, 611 A.2d 136 (App. Div, 1992)*, *aff'd. o.b.*, *132 N.J. 96, 622 A.2d 1305 (1993)*, the Court held that experts relying on epidemiological studies could provide sufficient reliable evidence for the causes of diseases in specific individuals to present the issue of causation to juries. *Landrigan* and *Caterinicchio* involved the relationship of asbestos to colon cancer; *Dafler* addressed the relationship of cigarette smoking and asbestos to lung cancer.

In *Landrigan*, an occupational asbestos exposure case, the trial court dismissed the case on the ground that there was a lack of medical evidence to establish asbestos exposure as the cause of the disease. The Appellate Division affirmed. The Supreme Court reversed and held that epidemiologists could help juries determine causation in toxic tort cases and rejected the proposition that epidemiological studies must show a relative risk factor of "2.0" before gaining acceptance by a court. *Landrigan, supra at 419*. (A discussion of epidemiology and relative risk begins at p. 12).

The Supreme Court in *Landrigan* ruled that a trial judge must consider all the scientific data, sources thereof, and the methodology **[*16]** by which an expert reaches a conclusion, "includ[ing] an evaluation of the validity both of the studies on which he relied and of his assumption that the decedent's asbestos exposure was like that of the members of the study populations." *Id at 420*. Additionally, the Supreme Court advised that "to determine the admissibility of the witness's opinion, [a] court, without substituting its judgment for that of the expert, should examine each step in [the expert's] reasoning." *Id. at 421*.

During the *Kemp* Hearing in these proceedings the court invited counsel to research what other courts have done on a relative risk factor of less than "2.0" and to submit their findings. The briefs furnished and the case law cited were very helpful. In reviewing the case law submitted by counsel, it is apparent that most courts across the nation — federal and state alike — discourage a dogmatic insistence upon a showing of a relative risk factor of "2.0" to support general causation. This court shares that perspective.

One case, cited by both sides, provided valuable guidance, namely *Magistrini v. One Hour Martinizing Dry Cleaning, 180 F. Supp. 2d 584 (D.N.J. 2002)*, *aff'd*, *68 F. Appx. 356 (3d Cir. N.J. 2003)*. The court in *Magistrini* noted "[a]s a general matter, the Rules of Evidence 'embody a strong and undeniable preference for admitting any evidence' **[*17]** that could potentially assist the trier of fact and *Rule 702* is liberally interpreted by the district courts." *Id. 595* (citations omitted). *New Jersey Evidence Rule 702* is identical to the Federal Rule. That said, the court in *Magistrini* also cautioned, "[t]he Courts inquiry 'must be solely on principles and methodology, not on the conclusions that they generate."' *Id.* (citing *Daubert v. Merrell Dow Pharms., 509 U.S. 579, 595, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993))*. In articulating the mental process of the "gatekeeper," the court in *Magistrini* cited the Supreme Court decision in *GE v. Joiner, 522 U.S. 136, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997)*, wherein Chief Justice Rehnquist advised trial judges:

> But conclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.
>
> *Id. at 146*.

A reading of the case law as to the weight attached

to a relative risk factor of less than "2.0" shows that it is only one of the factors to be considered by the court. What must also be examined are the foundational sources of the expert's **[*18]** opinions. As discussed herein (see p. 17) in connection with the court's examination of the "Bradford Hill" criteria, although no single criterion is dispositive, research performed prier to litigation and peer-reviewed essays on the scientific issue at hand are the basic means by which to demonstrate reliability. Where neither exists, an expert witness is obligated to explain to the court how she/he proceeded in arriving at his/her conclusions by referencing some objective source(s), *e.g.*, a peer-reviewed article in a reputable medical/science journal, the public pronouncements of an agency with respected authority on the issue, or a learned treatise on the issue, in order to demonstrate that she/he has followed the scientific method at the standard maintained by some recognized minority of scientists in his/her area of science.

Accordingly, as this court understands New Jersey law and our Supreme Court's holding in *Landrigan*, the admissibility of expert testimony in toxic tort cases "depends on the expert's ability to explain pertinent scientific principles and to apply those principles to the formulation of his or her opinion. Thus, the key to admission of the opinion is the validity **[*19]** of the expert's reasoning and methodology." *Landrigan, supra at 414*. Nonetheless, the Supreme Court noted that, traditionally, "plaintiffs have established a connection between tortious conduct and personal injuries through the testimony of medical experts who testify that the defendant's specific conduct was the cause of the plaintiffs' injuries[,]" but that "[t]oxic torts, however, do not readily lend themselves to proof that is so particularized." *Id. at 415*. Accordingly, plaintiffs in toxic tort cases "may be compelled to resort to more general evidence, such as that provided by epidemiological studies." *Id*. This court is, of course, bound by the holding in *Landrigan* that "when an expert relies on such data as epidemiological studies, the trial court should review the studies, as well as other information proffered by the parties, to determine if they are of a kind on which such experts ordinarily rely." *Id, at 417*. (In the course of analyzing the issues raised herein, the court has carefully read every epidemiological study cited by the witnesses and legal counsel at the *Kemp* Hearing).

Ten years after *Landrigan*, in *Kemp v. State of New Jersey, 174 N.J. 412, 430-32, 809 A.2d 77 (2002)*, the Supreme Court applied the *Rubanick* standard to a case involving an injury allegedly caused by vaccination, and implied its **[*20]** applicability to all tort cases in which a medical cause-effect relationship has not yet been confirmed by the scientific community but for which "compelling" evidence suggests that such a relationship does exist. In *Kemp*, the Supreme Court suggested that an *N.J.R.E. 104* hearing is the preferred procedural practice in every case involving an experts theory that has not yet achieved "general acceptance," finding that the trial court has an obligation, *sua sponte*, to conduct such a hearing and that the failure to do so is plain error.

Accordingly, from this court's perspective, the inquiry at a *Kemp* Hearing must be "flexible." Its focus must be on principles and methodology and not necessarily on the conclusions/opinions that such scientific methodology may generate. The trial court's role is to determine whether the expert's opinion is derived from a sound and well-founded methodology. "There must merely be *some expert consensus* that the methodology and the underlying data are generally followed by experts in the field." *Rubanick, supra at 450* (Emphasis added). Thus, at this *Kemp* Hearing, Plaintiffs' burden is to demonstrate that the methodologies used by their experts are consistent with valid scientific principles **[*21]** accepted in the scientific and medical communities.

Finally, the court is guided by the words of Justice Handler in *Rubanick, supra, 125 N.J. 451*, wherein he cautioned trial court judges that they must exercise restraint.

We do not believe that in determining the

soundness of the methodology the trial court should directly and independently determine as a matter of law that a controversial and complex scientific methodology is sound. The critical determination is whether comparable experts accept the soundness of the methodology, including the reasonableness of relying on this type of underlying data and information. *Great difficulties can arise when judges, assuming the role of scientist, attempt to assess the validity of a complex scientific methodology*.
(Emphasis added).

V. "BUILDING BLOCKS" OF THE SCIENTIFIC METHOD RELEVANT TO TALC-BASED POWDER AND OVARIAN CANCER

A *Kemp* Hearing is the intersection of the scientific method and the rule of law. If our court system is to be respected by the scientific community, then we must respect the scientific process. Essentially, the scientific method is the systematic pursuit of knowledge. This pursuit consists of those principles and procedures involved in the recognition **[*22]** and formulation of a problem, the collection of data through observation and experimentation, and the articulation and testing of a hypothesis by which to resolve the problem, and hopefully gain new knowledge useful to society.

What follows are the "building blocks" of the scientific method which the court must consider in evaluating Plaintiffs' experts' methodologies in arriving at their conclusions and opinions, and whether the same are "reliable." The key is consistent adherence to the scientific method. In addressing the issues to be resolved, the court has endeavored to faithfully apply the principles and tools of science to the issues at hand.

A. Epidemiological Studies

The two primary types of observational studies relevant to these proceedings (*viz*., epidemiology studies) are (1) cohort studies, and (2) case-control studies. Cohort studies compare the incidence of disease among individuals exposed to a substance with an unexposed group. Case-control studies examine the frequency of exposure in individuals who presently have the disease and compare them to a group of individuals who do not have the disease.

Epidemiologic studies provide "the primary generally accepted methodology **[*23]** for demonstrating a causal relation between a chemical compound and a set of symptoms or disease." See *Conde v. Velsicol Chem. Corp., 804 F. Supp. 972, 1025-26 (S.D. Ohio, 1992)*, *aff'd*., *295 F. 3d 1194 (11th Cir. 2002)*. When a scientific rationale doesn't exist to explain logically the biological mechanism by which an agent causes a disease, courts may consider epidemiologic studies as an alternate means of proving general causation. According to the *Reference Manual*, at page 723-24, large epidemiological studies present some of the strongest medical/scientific evidence. The typical use of large population-based studies is in connection with "general causation." As noted in the *Reference Manual* at page 623, general causation is concerned with "whether an agent increases the incidence of disease in a group and not whether the agent caused any given individual's disease." Nonetheless, the *Reference Manual* at page 552 cautions trial judges that "it should be emphasized that *an association is not equivalent to causation*." (Emphasis in the original text).

Epidemiologic studies attempt to identify agents that are associated with an increased risk of disease. Thus, the first question an epidemiologist must ask is whether or not an association exists between exposure to a substance and a particular disease. An association between exposure to an agent and a disease exists when the **[*24]** two occur together more frequently than they would by mere chance. In that situation, the association is referred to as *significant*. "Statistically significant" means that the scientific community recognizes that the association between two or more variables is caused by something other than "random chance." Once a significant association is observed, the scientist undertaking the study must assess the

strength of the association, plus whether the reason for the observed association is due to *bias, chance or a genuine effect*. A measure of the strength of an association in an epidemiological study can be expressed in terms of its "relative risk" (hereinafter "RJR"). R/R indicates the difference in the risk of contracting a disease in people exposed to a substance, as compared to those who are unexposed but are otherwise similar, in this case the American adult female population. Determining the R/R is important in understanding the results of a study because virtually every disease associated with a risk factor also occurs, at some rate, in the general population among study participants who are unexposed to the risk factor.

R/R is commonly calculated by dividing the risk of developing **[*25]** a disease observed in an exposed group by the risk observed in an unexposed, but otherwise similar, group. If the risks of the unexposed and exposed are the same, then the relative risk estimate (which mathematically is simply the former divided by the latter) is "1.0", also termed "null." The null value indicates that exposure is not associated with the disease in that study. Thus, an R/R of "1.0" means that the agent has no effect on the incidence of disease. Similarly, if the R/R estimate is "1.3," then risk appears to be 30% higher among the exposed compared to the non-exposed. When an R/R reaches "2.0," the risk has doubled, indicating that the risk is twice as high among the exposed group as compared to the unexposed group. As discussed in the *Reference Manual* at page 612, note 192, there exists "... considerable disagreement on whether a relative risk of 2.0 is required or merely a taking-off point for determining sufficiency ...".

In evaluating epidemiological studies, it is important to note that "[a]n association is not equivalent to causation. An association identified in an epidemiological study may or may not be causal. Assessing whether an association is *causal* requires an understanding of the strengths and weaknesses **[*26]** of the study's design and implementation, as well as a judgment about how the study findings fit with other scientific knowledge." *Reference Manual* at page 552-3. As cautioned by the *Reference Manual*, the closer the R/R is to the null (or the further it is from 2.0), the greater the concern for bias or confounding.

Generally, there are three reasons that a positive association may be observed: (a) bias (including confounding factors), (b) chance, and (c) real effect. Each must be evaluated to extract a valid message from the study. Evaluation of these factors measures the "internal validity" of an epidemiology study, *viz*., the extent to which a particular study's findings are viable and sound. "Bias" in epidemiology is systematic error, which includes "confounding bias." The underlying impact of these biases is to make the two groups being compared different in more ways than just the variable being studied. Sources of bias must be considered in interpreting an epidemiological study because bias can produce an erroneous association. *Reference Manual* at pages 591-3.

The record of the *Kemp* Hearing conducted by the court is replete with testimony, argument, and legal briefs regarding the significance to be attached to various studies conducted by **[*27]** epidemiologists on the possible association of talc-based products and ovarian cancer. Each side cited numerous studies to support its position. Nevertheless, this court's review of the various studies is informed by the admonishment of the *Reference Manual* at page 576:

> Common sense leads one to believe that a large enough sample of individuals must be studied if the study is to identify a relationship between exposure to an agent and disease that truly exists. Common sense also suggests that by enlarging the sample size (the size of the study group), researchers can form a more accurate conclusion and reduce the chance of random error in their results...With large numbers, the outcome of test is less likely to be influenced by random error, and the researcher would have greater confidence in the inferences drawn from the data.

B. Laboratory Studies on Talc and Cancer

To confirm a possible cause-and-effect relationship suggested by epidemiological studies, an exposure assessment can be conducted in order that the findings of those studies may be compared to the adverse health impacts predicted from exposure estimates and toxicological data from laboratory experiments.

Laboratory studies can be conducted using cells **[*28]** from animals or humans. Research involving a controlled environment, such as cell cultures in a test tube or in a petri dish, are called *in vitro* studies. Studies done on living organisms are called *in vivo* studies. There are many institutions around the world conducting laboratory studies focused upon the potentially causal relationship between various substances and cancer. Much can be learned from those studies.

Here, regarding Plaintiffs' claim of a specific causal relation between talc-based powder and ovarian cancer, laboratory studies can be performed on both human and animal cells to assess the impact of talc upon tissue and cells removed from both women and animals.

C. Cancer Biology and Research

The past generation has seen large strides made in understanding the pathways which cause human cancers. These "pathways" are essentially a molecular chain of events that cause human cancers. Scientists now have the ability to analyze many thousands of genes, and to study how a particular gene responds to various substances. This can be done in both human and animal cells, both *in vitro* and *in vivo*. In the process scientists can gain a better understanding of what triggers cancer. Thus, **[*29]** understanding how these pathways get turned on or turned off by the mutations in key genes is critical to understanding the rudimentary causes of cancer. As will be discussed hereinafter in connection with the testimony of Dr. Lewis Chodosh, there is a great deal to be learned from studying the biology of cancer. The biology of cancer and the research being done (and results from years past) are all relevant to any scientific inquiry into the alleged causal connection between talc-based powder and ovarian cancer.

D. Animal Studies

Another means by which to measure the toxicity of an agent in humans is through animal toxicology studies. The purpose of animal studies is not to predict what specific types of cancer a particular carcinogen might cause in humans, but rather to identify whether it can cause cancer at However, animal studies are of limited use in determining whether a particular substance causes a particular disease, or type of cancer, in humans. Generally, where both epidemiologic studies and animal toxicology are available, there is no universal rule for how to reconcile them. The scientific method dictates that careful assessment of the methodological validity and power **[*30]** of the epidemiologic evidence must be undertaken and the quality of the toxicological studies and the question of interspecies extrapolation and dose-response relationship must be also considered.

E. Agencies Which Study Cancer

Though cancer has plagued mankind throughout the history of civilization, it wasn't until the twentieth century that the U.S. Congress decided to take the lead in developing a permanent agency of government to encourage research into the causes and cures of cancer.

> In 1937, Congress established the National Cancer Act of 1937 to provide additional support for cancer research — it was the first time Congress had appropriated funds toward a non-communicable disease. The Act established the National Cancer Institute ("NCI") as the federal government's primary agency to address research and training needs for the cause, diagnosis, and treatment of cancer. NCI's responsibilities included (in part):
>
> • Conducting, coordinating, and promoting research and studies relating to the cause,

diagnosis, treatment, and prevention of cancer.
• Reviewing and approving grant applications to support promising cancer research.
...

• Collecting, analyzing, and disseminating the results **[*31]** of cancer research conducted in the United States and in other countries.

[The above can be found at: http://www.cancer.gov/about-nci-overview/history .]

In addition to the NCI, several other agencies and associations study and report to the public. As shown in Appendix E, those entities include: U.S. Food and Drug Administration, American Cancer Society, World Health Organization, International Agency Research on Cancer, and The American College of Obstetricians and Gynecologists. [NOTE: Each of these agencies has made public pronouncements which are inconsistent with, and/or unsupportive of Plaintiffs' claims that talc-based powder causes ovarian cancer.]

F. Bradford Hill Criteria

From the court's perspective, this "building block" is really the "mortar" for the scientific method. The Bradford Hill criteria should be acknowledged, either initially or by way of summary, in any discussion of the method(s) by which scientists seek new knowledge on a given scientific question. Because this court sees the criteria discussed below as "mortar" for building the conclusions in this analysis, it is the final item discussed.

In 1965, respected scientist and pioneer in medical statistics, Sir Austin Bradford Hill (1897-1991), made a speech before **[*32]** a group of colleagues wherein he attempted to articulate those essential benchmarks which the scientific community must consider in distinguishing between causal and non-causal explanations of observed associations. That speech is likely the most widely-published and quoted after-dinner speech delivered by a physician.

In determining whether an observed association between a chemical and a disease is causal (*i.e.*, general causation), Hill advised that scientists should be guided by various factors, which are often referred to as the "Hill criteria."

These factors include: (1) strength of association (*i.e.*, is the association strong and statistically significant?); (2) consistency of the relationship whether it has been repeatedly observed in other persons?) (3) specificity of association (*i.e.*, is there a particular association between the substance and the condition it purportedly causes?); (4) temporality (are the cause and effect bound in time, or as Hill states, "which is the cart and which is the horse?); (5) biological gradient (does the association reveal a dose-response curve?); (6) plausibility (*i.e.*, whether there exists a biologically plausible *mechanism* by which the agent **[*33]** *could* cause the disease?); (7) coherence (does cause-and-effect interpretation of the data conflict with the history and biology of the disease?); (8) experiment (is the frequency of the associated events affected by reducing the amount of the suspected substance?); (9) analogy (should science anticipate similar results from a consideration of alternative explanations?). Here, regarding talc-based products and ovarian cancer, though most of the factors come in for consideration to varying degrees; this is particularly true factors 1, 2, 5, and 6. [NOTE: When, as here, the R/R is significantly less than "2.0", factor #6 is essential.]

Finally, it should be noted that it is unlikely that Hill intended that scientists should be inflexibly bound to his criteria. There is little doubt in the scientific community that he encouraged that the seven identified considerations be applied flexibly. That said, a final portion of his speech is worthy of quoting verbatim.

> All scientific work is incomplete — whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. *That does not confer upon us a freedom to ignore the knowledge we*

already ***[*34]*** *have*, or to postpone the action it appears to demand at a given time. (Emphasis added).

VI. PRELIMINARY OVERVIEW OF EXPERT TESTIMONY AND ANALYSIS OF THE TOTALITY OF THE EVIDENCE PRESENTED

This court is ever mindful of its role as a "gatekeeper" and the "great difficulties" that can arise for a trial judge in ruling on the admissibility of expert testimony. The analysis for determining what proofs may be presented to a jury must be in accordance with the standards expressed by our Supreme Court; that is the frame of reference by which the information presented by counsel and the experts must be scrutinized. The court had the opportunity to observe closely the nine expert witnesses presented by the parties. Much was learned from each witness; nonetheless, a preliminary observation sets the foundation for all that follows.

Throughout these proceedings the court was disappointed in the scope of Plaintiffs' presentation; it almost appeared as if counsel wished the court to wear blinders. Plaintiffs' two principal witnesses on causation, Dr. Daniel Cramer and Dr. Graham Colditz, were generally dismissive of anything but epidemiological studies, and within that discipline of scientific investigation **[*35]** they confined their analyses to evidence derived only from small retrospective case-control studies. Both witnesses looked askance upon die three large cohort studies presented by Defendants. As confirmed by studies listed at Appendices A and B, the participants in the three large cohort studies totaled 191,090 while those case-control studies advanced by Plaintiffs' witnesses, and which were the ones utilized in the two meta-analyses performed by Langseth and Terry, total 18,384 participants. As these proceedings drew to a close, two words reverberated in the court's thinking: "narrow and shallow." It was almost as if counsel and the expert witnesses were saying, *Look at this, and forget everything else science has to teach us*.

The *Reference Manual* expressly cautions against a narrow and shallow examination of the science supporting Plaintiffs' contentions. "The critical difference between cohort studies and case-control studies is that cohort studies begin with exposed people and unexposed people, while case-control studies begin with individuals who are selected based on whether they have the disease or do not have the disease and their exposure to the agent in question is measured." **[*36]** (p. 557). Additionally, Section IV. B. of the *Reference Manual* warns of bias, particularly "information bias" of the participants. "In a case-control study, potential information bias is an important consideration because the researcher depends on information from the past to determine exposure and disease and their temporal relationship." (p. 585).

Equally troubling is Plaintiffs' failure to address meaningfully the other fields of scientific inquiry — or "building blocks" - in support of their assertion of general causation, *e.g.*, laboratory studies on talc, cancer biology, and animal studies. Most critical is their failure to provide a coherent explanation to support their hypothesis for biologic plausibility, which is #16 of the Hill criteria, to wit, "plausibility".

Neither Dr. Cramer nor Dr. Colditz expressed much interest in explaining just how it is that talc-based powder supposedly causes cancer in the ovaries, or for that matter any part of the human anatomy. "Inflammation" was used almost as a talisman that supposedly explained everything the court needed to know. Stated in lay terms, Dr. Cramer's and Dr. Colditz's postulation, essentially, is as follows: *The talc flows upstream* ***[*37]*** *and lodges in Me ovaries; it irritates cells in the ovaries, causes inflammation, which in turn causes immunosuppression, and the inescapable result is cancer*. Positing that premise (which the court does not), both witnesses ignore the fact that that Dr. Godleski conceded on cross examination that he did not observe inflammation in any of the tissue —of either Plaintiff - that he examined.

> Q Doctor, you agree also that neither Mrs. Carl nor Mrs. Balderrama' s treating pathologists noted any talc-related inflammatory reactions in their reports in these cases?
> A That's correct.

(See generally the testimony of 8/9/16; see P129, LI thru P130, L21).

A cornerstone of the "talc causes cancer" hypothesis is "inflammation," yet none was present in any of the tissue samples studied.

Incident to the meager width and depth of the investigation employed by Plaintiffs' experts in this litigation was the failure to address several questions arising from the proffered evidence. These questions illustrate the flaws in the methodology of Plaintiffs' experts.

> 1. Those epidemiological studies showing a potential link between talc-based powder and ovarian cancer repeatedly rank serous ovarian cancer as the most **[*38]** likely type of cancer that may result among talc users. Dr. Cramer confirmed that in his testimony; "...invasive serous cancer, [is] the type most commonly associated with talc use." (Testimony of 8/8/16; see P320, L19) Neither Plaintiff was diagnosed with this condition. *Why was there no testimony presented to address this obvious incongruity*?
>
> 2. Talc was purportedly found in tissue surgically removed from each of the Plaintiffs. It was argued by Plaintiffs and their experts that inflammation is the root cause of all cancers. Yet there is nothing in the records nor expert reports demonstrating that the tissue samples were inflamed. *Why was there no testimony presented to address this obvious question*?
>
> 3. Positing Plaintiffs' contention that talc particles travel naturally through the female anatomy, from the perineum to the ovaries, then, *a fortiori*, the potential for talc particles to lodge elsewhere along the reproductive tract and create similar conditions would be apparent. Yet the only portion of the reproductive tract in which talc has purportedly caused cancer is the ovaries. Nothing was presented showing an increase in the other gynecologic cancers such as vaginal cancer, cervical **[*39]** cancer, uterine cancer, or fallopian tube cancer, which is what one would reasonably expert. *Why was there no testimony presented to address this obvious conundrum*?

Summary of Dr. Chodosh's Testimony

As part of its preliminary overview of the expert testimony presented, the court is compelled to highlight the testimony of one witness in particular. Dr. Chodosh's testimony for Defendants was akin turning on the lights in a dark room. The failure of Plaintiffs' experts to articulate a plausible hypothesis for the biological mechanism by which talc purportedly causes ovarian cancer is a serious deficiency. After hearing Dr. Chodosh's testimony, it is apparent to the court that there was no articulation of a plausible hypothesis because it is unlikely that one can be made. Dr. Chodosh's testimony illustrates the huge hole in Plaintiffs' scientific methodology, namely, the failure to consider the biology of cancer. Dr. Chodosh's testimony and the scientific studies (see Appendix D) upon which he relies in formulating his opinions appear to support a reasonable hypothesis that talc does not cause cancer because it cannot cause cancer.

What follows are the most significant conclusions from Dr. **[*40]** Chodosh's testimony, none of which were addressed by anything Plaintiffs' experts presented, nor diminished in their impact on cross-examination.

> 1. Talc is *inert*. "...talc does not change gene expression in ovarian cells. Treating ovarian cells with talc didn't change the expression." (Testimony of 8/19/16; see P71, L2 thru P77, L13).
>
> 2. Talc is an anti-cancer property because it

inhibits the formation of blood cells, and it cannot cause mutations.

Q What do they show just in some --

A In a thumbnail, it basically shows that talc actually inhibits the formation of blood vessel growth.

Q Which is an anticancer property of talc?
A Yes, that would be an anticancer property.

(See generally the testimony of 8/19/16; see P33, L23 thru P34, L7 and P39, L10 thru P53, L8).

See also the study by N. Najmunnis, et al., *Talc mediates angiostasis in malignant pleural effusions via endostatin induction* at Appendix D wherein these scientists concluded: "In conclusion, talc alters the angiogenic balance in the pleural space from a biologically active and angiogenic environmental to an angiostatis milieu. Functional improvement following talc poudrage in patients with malignant pleural effusions may, in part, **[*41]** reflect these alterations in the pleural space."

3. Talc induces cancer cells to apoptosis but not to normal cells. (Testimony of 8/19/16; see P41, L5 thru P45, L3 and P143, L18 thru P145, L7).

4. It's universally accepted that mutations in critical genes is the mechanism that causes cancer, and talc doesn't cause mutations. (Testimony of 8/19/16; see P52, L22 thru P56, L9).
5. "Inflammation" is an extremely complex issue and it is unclear whether chronic inflammation is sufficient to induce cancer in the absence of a carcinogen. (Testimony of 8/19/16; see P177, L11 thru P181, L10).

VII. FOOD and DRUG ADMINISTRATION LETTER ON TALC

Much was made by counsel for both sides in their questioning of witnesses during the several days of the *Kemp* Hearing with regard to a letter from the Food and Drug Administration (FDA), dated April 1, 2014, hereinafter "the FDA letter." The FDA letter was in reply to the "Citizen Petitions" filed by Samuel S. Epstein, M.D., of the University of Illinois, School of Public Health, on behalf of the "Cancer Prevention Coalition." Said petitions (dated November 17, 1994 and May 13, 2008) requested the FDA to require all cosmetic talc products to bear a warning label. **[*42]** Particularly, with regard to talcum powder, the Coalition requested a prominent warning reading as follows: "Frequent talc application in the female genital area is responsible for major risks of ovarian cancer."

The court perused the FDA's letter on multiple occasions. Depending upon one's perspective, the letter can be cited for a great deal of importance, or, it might be said that the letter provides very little new information of significance to the issues that must be addressed herein. This court's reading falls into the latter category

There was limited discussion of the FDA's statutory and regulatory authority during the *Kemp* Hearing. Yet, there is a need to place the letter and the FDA's role into proper context. The pertinent regulation dealing with labeling of talcum powder or any other "cosmetic" product is set forth of Title 21 of the Federal Register. It states in pertinent part:

§740.1 Establishment of warning statements.
(a) The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product.

(b) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested **[*43]** person who has submitted a petition, may publish a proposal to establish or amend, under subpart B of this part, a regulation prescribing a warning for a cosmetic. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in part 10 of this

chapter, and will be published for comment if it contains reasonable grounds for the proposed regulation.

Subpart "(a)" of Section 740.1 was discussed with one witness, and comments were made by counsel concerning the same. Yet there was no discussion by Plaintiffs' experts with regard to *subpart "(b)*." That subpart requires petitions such as those filed by Dr. Epstein and the Cancer Prevention Coalition to *include an adequate factual basis to support the petition*. Subpart "(b)" states that upon submission of an "adequate factual basis," the Commissioner of the FDA "either on his own initiative or on behalf of any interested person who has submitted a petition" has the authority to "publish a proposal to establish" a warning label for a "cosmetic product." That would include talcum powder. As noted by Deputy Director Steven M. Musser, Ph.D., the petitions were denied because they lacked sufficient "evidence **[*44]** of a causal association between talc use in the perineal area and ovarian cancer." In denying the petitions, the "FDA found" and articulated six points which the agency concluded were supported by its review of "an expanded literature search."

Relevant to the court's analysis are findings #2 and #4 of the FDA letter. Finding #2 expressed concerns with biases in the design of studies and uncontrolled confounding. It also noted that "no single study has considered all the factors that potentially contribute to ovarian cancer". Finding #4 states in relevant part, "[a] cogent biological mechanism by which talc might lead to ovarian cancer is lacking..." Nothing was presented by Plaintiffs' expert with regard to these two critical findings of the FDA.

The FDA letter is essentially an acknowledgement of the status quo, based upon its own "expanded literature search." In short, the real rationale that can be drawn from the FDA letter is that if there existed sufficient evidence linking talc causally to ovarian cancer, *viz., an adequate factual basis to support* such a postulation. the FDA has the resources and regulatory authority to mandate a warning label for talcum powder.

VIII. DEFICIENCIES **[*45]** IN DR. COLDITZ'S METHODOLOGY

Dr. Graham Colditz is a brilliant scientist and a dazzling witness. His vocal inflection, cadence, and adroit use of histrionics are extremely effective. Dr. Colditz's reputation for his breadth of knowledge about cancer and the esteem in which he is held by his peers is well deserved. Yet, at times, it seemed that issues raised in these proceedings, and the questions posed to him, were a bit mundane for a scientist of his caliber.

At page 10 of his report of July 31, 2015, Dr. Colditz discusses "biologic plausibility." His discussion of the subject entails fewer than 75 words. He cites a total of four peer-reviewed articles in arriving at his opinion: "Thus it is established that talc can travel to the ovary, it causes an inflammatory response, and this mechanism is consistent with the increase of ovarian cancer that is observed."

Scrutiny of the articles cited in Appendix C does not support his conclusion. What follows is a brief discussion of the aforesaid learned treatises referenced by Dr. Colditz.

Roberta B. Ness: This paper is limited to a review of existent epidemiologic literature in the English language on the risk and protective factors for ovarian **[*46]** cancer and "proposes a novel hypothesis that a common mechanism underlying this disease is inflammation." Though talc exposure is mentioned, along with other theories of what may cause ovarian cancer, this paper does not discuss the means by which *talc can travel to the ovary*, nor does it discus the means by which talc causes *an inflammatory response* in the cells of the ovaries.

Jack Cuzik: This paper is limited to use of aspirin and NSAIDs for cancer prevention. This treatise does not discuss the means by which *talc can travel to the ovary*, nor does it discuss the means by

which talc causes *an inflammatory response* in the cells of the ovaries.

Britton Talbert: This paper is limited to the "multiple lines of evidence" which "suggest that ovarian cancer may be related to chronic inflammation." In short, "this pooled analysis supports the hypothesis that regular aspirin use reduces ovarian cancer risk." This treatise does not discuss the means by which *talc can travel to the ovary*, nor does it discuss the means by which talc causes *an inflammatory response* in the cells of the ovaries.

Britton Talbert: This paper is limited to a discussion of the pro-inflammatory mechanisms that may explain **[*47]** "the increased risk linked to more lifetime ovulations, endometriosis, and exposure to talc and asbestos, as well as the decreased risk with non-steroidal anti-inflammatory drugs." This treatise does not discuss the means by which *talc can travel to the ovary*, nor does it the means by which talc causes *an inflammatory response* in the cells of the ovaries.

Even the most generous reading of these four cited articles reveals that none of them proffers an articulation of a hypothesis — nor a means by which to test the same — setting forth a biologic mechanism by which talc-based powder may/can/possibly does cause ovarian cancer. Dr. Colditz's reliance upon these four treatises supports a finding by this court that he has failed to make a systematic review of the scientific literature and has ignored the rudiments of the scientific method in arriving at his conclusion that, "[t]hus it is established that talc can travel to the ovary, it causes an inflammatory response, and this mechanism is consistent with the increase of ovarian cancer that is observed."

Further, with regard to "biologic plausibility," the court recalls Dr. Colditz's answer to the questions posed from the bench on this issue. **[*48]** Those questions dealt with a hypothesis on biologic causation postulated by Dr. Cramer. The exchange between the court and Dr. Colditz reads as follows:

THE WITNESS: Yes, it is Dr. Cramer's study.

THE COURT: Then turn to page 355. I'm determined to get an answer to this question. I asked it yesterday, and I wasn't able to get an answer. 355. Look at the second column. And then let's go to the last long sentence. "We have also proposed that talc use during periods of ovulation may carry greater risk, based upon the hypothesis that ovarian surface epithelial disruption and repair accompanying ovulation might allow talc to become entrapped within the inclusions cysts that form with ovulation." First question is, explain that to me in laymen's terms.
THE WITNESS: Wow. Ovulation.
THE COURT: A good scientist can do that. I'm sure you will. I understand ovulation.

THE WITNESS: You understand the ovulation. Right? That's -- and so he's saying that with ovulation and then in that disrupted epithelium, the presence of talc can more likely get --
THE COURT: How?
THE WITNESS: -- into a cell --
THE COURT: How? What's the cyst? What's an inclusion cyst?

THE WITNESS: Oh, so the -- this is the cyst that develops **[*49]** in an ovary that would have a talc particle in it as an inclusion cyst. So he's saying that with sort of the surface of the ovary has to repair each time it pops. And so there's --
THE COURT: That's a traumatic experience for that part of the body.
THE WITNESS: Yeah, right. And so there's inflammatory response.
THE COURT: Go ahead.

THE WITNESS: And so you got some macrophages and other things working to clean up and repair the epithelium. And if you've got the talc present at that time --
THE COURT: If you have it present at that time.
THE WITNESS: -- if you've ovulated, you've

got higher likelihood is, I think, what he's trying to say.
THE COURT: And based upon your readings in preparation for your report, did you find any other peer-reviewed articles where Dr. Cramer discussed this hypothesis? And coupled with that, has anybody else discussed this hypothesis? Because if they do, I want to read it.

THE WITNESS: So obviously others have discussed the description of talc in ovary. The IARC and others describe inflammation and the carcinogenic process.
THE COURT: I've heard lots of testimony. But I'm talking about this hypothesis.
THE WITNESS: This actual --

THE COURT: I'm not asking you to defend **[*50]** this hypothesis.
THE WITNESS: No, no.
THE COURT: I'm asking you to tell me has anybody else discussed it so I can read it.
THE WITNESS: I can't think of this specific mechanism for getting in -- being described.
THE COURT: So you don't know of any other study where Dr. Cramer did or anybody else did?
THE WITNESS: To look at the inclusion cysts?
THE COURT: That's what it says.
THE WITNESS: No.
THE COURT: Okay. Then I still don't have an answer to my question.
THE WITNESS: Then you don't. It's a great question.
THE COURT: It doesn't mean it's a good question. It just means I don't have an answer to it.
THE WITNESS: This is why there's got to be continuing studies to understand this whole process better.

(Testimony of 8/16/16, P312, L13 thru P315, L19).

To summarize this court's understanding of Plaintiffs' inability to explain the biological mechanism for how talc causes cancer, Dr. Colditz noted candidly, "This is why there's got to be continuing studies to understand this whole process better."

Though there are additional deviations from the scientific method included in Dr. Colditz's report — namely, the manner in which he blithely passes over most of the Hill criteria — the most egregious may **[*51]** be his failure/refusal to discuss *strength* of association, and how the same supports general causation. Repeated use of the term "significant" with regard to the R/R adds something to the discussion, but not much. As noted above, this court cannot be inflexibly bound by a R/R of "2.0" nor are the Hill criteria. A review of Dr. Colditz's testimony — both on direct and cross-examination — fails to establish a single instance in which he states that any number less than "2.0" for the R/R equates to sufficient strength to find a causal relation. His testimony supports neither general nor specific causation, nor does it address the question of where or whether a "significant" relationship becomes "causal."

Finally, Dr. Colditz's expert opinion is *ipse dixit* and has all the earmarks of a made-for-litigation presentation. We need look no further than his own past writings. *First*, in 2000 in his peer-reviewed article entitled, "Prospective Study of Talc and Ovarian Cancer," he concluded, "[o]ur results provide little support for any substantial association between perineal talc use and ovarian cancer risk overall..." *Second*, in his "2004 Handbook of Cancer Risk Assessment and Prevention," he lists **[*52]** talc as a "factor under study" in lieu of a modifiable factor which increases the risk of ovarian cancer. *Third*, as of 2011, on the website of the Alvin J. Siteman Cancer Center of which he is the Associate Director, the consensus of the Siteman scientific panel — which included both Dr. Colditz and Dr. Cramer — concluded that it was not appropriate to list talc as a risk factor on the "Your Disease Risk" portion of the website.

There is no challenge to Dr. Colditz's

qualifications, nor that his testimony is relevant. Yet from the court's perspective, there are significant gaps in his methodology and analysis. He has committed the very error which Hill warned scientists against, namely, that the results of their research "...does not confer upon us a freedom to ignore the knowledge we already have." Dr. Colditz has overlooked the knowledge to be learned from laboratory research regarding the biology of cancer.

Applying the standards established in *Rubanick, supra, 125 N.J. at 449*, and *Landrigan, supra, 127 N.J. at 420-1*, the court concludes that the significant deficiencies in Dr. Colditz's methodology and analysis herein described, render his opinions inadmissible in these proceedings, and that the Defendants' motion to bar the testimony of Dr. Colditz **[*53]** is hereby GRANTED.

IX. DEFICIENCIES IN DR. CRAMER'S METHODOLOGY

Dr. Cramer is a distinguished professional. His commitment to medical science generally, and to learning more about the potential health consequences to women from the frequent use of talcum powder in particular, have been unswerving throughout his career. Few people possess the knowledge he has acquired from case-control studies regarding the potential effects of talc *vis a vis* ovarian cancer. His passion for this subject is palpable and exemplary.

Dr. Cramer's study of this subject together with his examination and his analysis of the results of many case-control studies addressing the relationship between talc and ovarian cancer date back more than 30 years. In July, 1982 he published his initial peer-reviewed article on this subject entitled, "Ovarian Cancer and Talc: A Case-control Study." Over the past 34 years, Dr. Cramer has authored and co-authored numerous peer-reviewed articles on talc. He has also conducted several meta-analyses of other epidemiology reports. All those studies appear to demonstrate a consistent, albeit uniformly weak, association between talc and ovarian cancer.

Dr. Cramer is highly qualified and **[*54]** his testimony is relevant. Yet from the court's perspective, there is a large gap in his methodology. Dr. Cramer has totally ignored laboratory research regarding the biology of cancer and the ameliorative effects of talc on cancer. He has made the error that Hill expressly warned scientists against, *viz*., that the results of their research "...does not confer upon us a freedom to ignore the knowledge we already have."

As discussed above, the research and existing studies cited in the testimony of Dr. Chodosh dismantled the premise of Dr. Cramer's opinions on the causal association between talc-based products and ovarian cancer. Dr. Cramer's failure to address the opinions of Dr. Chodosh and the results of laboratory research on the ameliorative effects of talc on cancer highlights the serious flaws in his methodology.

For purposes of this *Kemp* Hearing, the court must consider whether Dr. Cramer's testimony is sufficiently reliable to be presented to a jury. Defendants attack his opinions on both *general* and *specific* causation.

On the issue of *general causation*, Defendants attack the odds ratios (O/R) established in his report. Dr. Cramer notes that in general, his research — relying **[*55]** almost entirely upon case-control studies - confirms that there is an O/R of 1.29 between perineal talc use and ovarian cancer. As indicated in his report, Dr. Cramer performed a case-control study to generate his final conclusions. In both his report and in his testimony, Dr. Cramer opines that the causal association between ovarian cancer and the use of talc has been "significant" and consistent for 30 years. The O/R of 1.29 reported by Dr. Cramer is admittedly "weak" and neither he nor any other witness explained when/how a "significant" association becomes causal?

A retrospective case-control study is commonplace in the field of epidemiology, but as noted by the *Reference Manual* at page 576 such studies are

considered less reliable than a prospective cohort study. Yet, that is almost entirely where Dr. Cramer devotes his research. According to Dr. Cramer, there have been 19 peer-reviewed scientific articles addressing the talc and ovarian cancer association since 1982. More recently there have been three very large cohort studies whose number of participants dwarfs those of the case-controls studies. (See Appendix A). Undermining the reliability of his testimony, Dr. Cramer is rigidly dismissive of the knowledge **[*56]** to be gained from the much larger cohort studies. On cross-examination, when asked if he had performed a meta-analysis of the three large cohort studies, he tartly replied, "I have not done that. The defense is very capable of doing that themselves." (Testimony of 8/8/16; see P324, L1 thru L8. See also his testimony at P199, L24 thru P200, L5).

Most troubling to the court is the effort made by Dr. Cramer to use epidemiology to prove *specific* causation. As noted by the *Federal Manual* at page 553, trial judges are warned of the overreliance upon such studies, "[a] final caveat is that employing the results of group-based studies of risk to make a causal determination for an individual plaintiff is beyond the limits of epidemiology." And again, the *Federal Manual* cautions, "[e]pidemiology is concerned with the incidence of disease in populations, and epidemiologic studies do not address the question of the cause of an individual's disease. This question, often referred to as specific causation, is beyond the domain of the science of epidemiology." (p. 608). In short, Dr. Cramer' s methodology appears to be litigation driven rather than objectively and scientifically grounded.

The court uses the phrase *made-for-litigation* methodology **[*57]** for a reason. In all his prior peer-reviewed articles, Dr. Cramer never once stated that he believes talc causes ovarian cancer; not in his articles of 1982, 1999, 2000 (with Gertig) and 2007 does he make such an assertion. In fact, in his study of 2007, he concluded, "[w]e are not claiming that a causal relationship between ovarian cancer and talc is proven for this case or in general." Yet now, after having never made such a claim, he asserts here not only general causation, but specific causation as to both Plaintiffs, and purports to do so by re-analyzing old studies and subjectively mingling the various risk factors for each Plaintiff in order to prove ovarian cancer *by the numbers*. This "methodology" is not one based upon "prolonged, controlled, consistent and validated experiences". *Rubanick at 436*.

A final issue which must be addressed with regard to specific causation is the detailing of a hypothetical etiology of the disease in question and how the alleged substance is the malefactor. In his study of 1999 (See Appendix B), Dr. Cramer — in passing — made a partial articulation of a hypothesis for the biological mechanism by which talc purportedly causes ovarian cancer. That partial articulation **[*58]** is set forth in a single sentence which reads:

> We have also proposed that talc use during periods of ovulations may carry greater risk, based on the hypothesis that ovarian surface epithelial disruption and repair accompanying ovulation might allow talc to become entrapped within the inclusion cysts that form with ovulation. (p. 355).

This is the closest Dr. Cramer has ever come to postulating a hypothesis for the causal link between talc and ovarian cancer. He does not allude to this hypothesis in either the Carl or the Balderamma reports. Nor was he asked about this hypothesis by counsel on direct-examination.

Instead of a plausible explication of a hypothesis setting forth the biological mechanism of the causal link between talc-based powder and ovarian cancer, what the court received was a *made-for-litigation* methodology, to wit, the subjective mingling of risk factors to advance the base-line relative risk for each of the Plaintiffs (as members of the U.S. population) from 1.29 to 1.75 (Carl) and 1.79 (Balderamma). The knowledge learned to date from epidemiology studies involving talc and ovarian

cancer is insufficient to prove ovarian cancer *by the numbers*.

Each of the Plaintiffs **[*59]** had significant risk factors for ovarian cancer to which Dr. Cramer's testimony showed a stark indifference. Ms. Carl had the following risk factors: obesity, nulliparity, infertility, past use of an IUD, psychotropic medication, smoking, and exposure to hair dye. Ms. Balderamma had the following risk factors: obesity, nulliparity, irregular cycles, early menarche (age 11), polycystic ovarian syndrome, past use of an IUD, and a potential BRCA gene diagnosis.

Despite his failure to eliminate — or make an objective accounting of — those multiple risks, Dr. Cramer leaps to specific causation *by the numbers*. He is not concerned that he hasn't even attempted to postulate a plausible biological hypothesis for how talc causes ovarian cancer as urged by factor #6 of the Hill criteria. His opinions rely upon an incomplete/irregular methodology unlike anything upon which his peers would rely, and appear to be grounded only in his instincts and personal predilections. In short, the mingling of various risk factors and the purported "synergy" between talc and other health conditions is highly speculative and does not conform to any methodology utilized in the scientific community.

Finally, Dr. Cramer **[*60]** and Plaintiffs' counsel would be better served to heed the wisdom contained in the FDA Letter of April 1,2014. Finding #4 of "Epidemiology and Etiology Findings" reads in pertinent part: "A cogent biological mechanism by which talc might lead to ovarian cancer is lacking..." Hill criterion #6, to wit, plausibility (*i.e.*, whether there exists a biologically plausible *mechanism* by which the agent *could* cause the disease?) requires Plaintiffs' experts to articulate and support/defend a plausible *mechanism* by which talc *could* cause ovarian cancer. Their failure to do so is decisive in the court's analysis.

Applying the standards established in *Rubanick, supra, 125 N.J. at 449*, and *Landrigan, supra, 127 N.J. at 420-1*, the court concludes that the significant deficiencies in Dr. Cramer's methodology and analysis herein described, render his opinions inadmissible in these proceedings, and that the Defendants' motion to bar the testimony of Dr. Cramer is hereby GRANTED

X. RULING

As is true of most adversarial proceedings, the written reports and testimony of Plaintiffs' experts are much like a patch-work quilt; individual pieces that when sewn together create a single blanket. If well sewn, the blanket covers the issues required to meet Plaintiffs' burden of **[*61]** proof. Positing, for the sake of discussion, that each piece of cloth is sound, the fragments cannot become a quilt without thread. Without a clearly stated, demonstrable hypothesis of specific causation, grounded in a reliable methodology, there is no thread and the pieces of cloth remain disparate.

Accepting, for the sake of discussion, that the case-control studies relied upon by Dr. Cramer — to the exclusion of cohort studies, laboratory studies, cancer biology and the pronouncements of those agencies that study cancer — convey an inference that there is some type of causal association between talc and ovarian cancer, it means nothing without a hypothesis of specific causation, No witness for Plaintiffs ventured to articulate just how it is that talc in the ovaries, or, what it is about talc in the ovaries, that sets off a chain of events which purportedly causes ovarian cancer. Uttering the term inflammation does not explain the etiology of ovarian cancer, nor can the manipulation of numbers serve as a hypothesis for specific causation. Absent the thread, there is no quilt.

As the proponent of the evidence on general and specific causation, "the plaintiff bears the burden of establishing **[*62]** admissibility." *Kemp, supra, 174 N.J. at 429*. As discussed, the testimony of Plaintiffs' experts suffers from multiple deficiencies, the most salient of which are the narrowness and shallowness of their scientific inquiries and the evidence upon which they rely.

Their peers in the scientific community would not rely upon such limited information.

Ultimately the admissibility of these experts' opinions depends "on the trial court's assessment of both [their] qualifications and [their] methodology." *Landrigan, supra, 127 N.J. at 422*. "The key to the admission of the opinion is the validity of the expert's reasoning and methodology." *Id. at 414*. Though both Plaintiffs' experts are eminently qualified, their areas of scientific inquiry, reasoning, and methodology are slanted away from objective science and towards advocacy. It is this court's conclusion that the opinions expressed by Plaintiffs' experts fail to demonstrate "that the data or information used were soundly and reliably generated and are of a type reasonably relied upon by comparable experts." *Rubanick, supra, at 447*.

For the reasons stated herein, the Defendants' motion to bar expert testimony and for entry of summary judgment as to both the Carl and Balderrama matters are hereby GRANTED.

With regard to the other expert **[*63]** witnesses of the Plaintiffs as well as Plaintiffs' cross-motions to bar the Defendants' experts, the Court will neither opine nor rule on the same. In light of the foregoing ruling, said petitions are of no practical significance and are deemed MOOT.

Date of Decision: 9/2/16

/s/ Nelson C. Johnson

NELSON C. JOHNSON, J.S.C.

TALC-BASED POWDER PRODUCTS LITIGATION

ORDER

THIS MATTER having come before the court on Defendants' motions to bar expert testimony; and Defendants having filed companion motion(s) for summary judgment seeking dismissal of Plaintiffs' Complaints in the event the motion(s) to bar testimony are granted; and Plaintiffs having filed cross motions to bar Defendants' expert testimony; and the court having conducted a plenary hearing on August 8, 9, 11, 12, 15, 16, and 19, 2016, at which time the court heard from Mark C. Haggerty, Esquire, Michael R. Klatt, Esquire, Gene M. Williams, Esquire, Susan M. Sharko, Esquire, Julie Tersigni, Esquire, Loma Dotro, Esquire, Hunter K. Ahern, Esquire, Kenneth J. Ferguson, Esquire, and Ann Thorton Field, Esquire, on behalf of Defendants in support of their application; and Plaintiffs opposing this motion, Richard Golomb, Esquire, Ruben Honik, **[*64]** Esquire, Ted G. Meadows, Esquire, David B. Dearing, Esquire, Timothy W. Porter, Esquire, Michelle Parfitt, Esquire, and Paul R. D'Amato, Esquire, appearing; and the court having received expert testimony and oral argument of counsel conducted pursuant to *Evid. R. 104* and *702*, the standards articulated by our Supreme Court in *Kemp vs. The State of New Jersey 174 N.J. 412, 809 A.2d 77 (2002)*, and for the reasons stated in the Opinion of even date herewith; and for good cause shown;

IT IS ON THIS 2nd DAY OF SEPTEMBER, 2016, ORDERED as follows:

1. Defendants' motion to bar the testimony of Dr. Graham A. Colditz is hereby GRANTED.
2. Defendants' motion to bar the testimony of Dr. Daniel W. Cramer is hereby GRANTED.
3. As a consequence of the aforesaid rulings, Defendants' motion for summary judgment as to Plaintiff, Brandi Carl, is hereby GRANTED. Plaintiff, Carl's Complaint is dismissed with prejudice.
4. As a consequence of the aforesaid rulings, Defendants' motion for summary judgment as to Plaintiff, Diana Balderrama, is hereby GRANTED. Plaintiff, Balderrama's Complaint is dismissed with prejudice.

5. As a consequence of the aforesaid rulings, Defendants' motions to bar testimony of other expert witnesses are deemed MOOT.

6. As a consequence of the aforesaid rulings, **[*65]** Plaintiffs' cross-motions to bar Defendants' experts are deemed MOOT.

/s/ Nelson C. Johnson 9-2-16

NELSON C. JOHNSON, JSC

APPENDIX A

Cohort Studies

(1) Douching, Talc Use, and Risk of Ovarian Cancer

Gonzalez, Nicole, et al., *Epidemiology*, (The "Sister Study"), June 20, 2016.

Abstract

Background: Douching was recently reported to be associated with elevated levels of urinary metabolites of endocrine disrupting phthalates, but there is no literature on douching in relation to ovarian cancer, Numerous case-control studies of genital talc use have reported an increased risk of ovarian cancer, but prospective cohort studies have not uniformly confirmed this association. Behavioral correlation between talc use and douching could produce confounding.

Methods: The Sister Study (2003-2009) enrolled and followed 50,884 women in the US and Puerto Rico who had a sister diagnosed with breast cancer. At baseline participants were asked about douching and talc use during the previous 12 months. During follow-up (median of 6.6 years) 154 participants reported a diagnosis of ovarian cancer. We computed adjusted hazard ratios (HR) and 95% confidence intervals (CI) for ovarian cancer risk using the Cox proportional **[*66]** hazards model.

Results: There was little association between baseline perineal talc use and subsequent ovarian cancer (HR: 0.73 CI: 0.44, 1.2). Douching was more common among talc users (OR: 2.1 CI: 2.0, 2.3), and douching at baseline was associated with increased subsequent risk of ovarian cancer (HR: 1.8 CI: L2, 2.8).

Conclusions: Douching but not talc use was associated with increased risk of ovarian cancer in the Sister Study.

Discussion

... with the exception of the finding that talc use was positively associated with serous ovarian cancer in the Nurses' Health Study, the prospective studies have net provided evidence supporting an association between talc use and ovarian cancer overall or between talc use and ovarian cancer overall among post-menopausal women.

... Because Sister Study participants all have a first-degree family history of breast cancer, they are more likely than the general population to develop ovarian cancer ... by design, we excluded women with a previous history of breast cancer ....

Our review of the literature suggests that our study is the first to examine the association between douching and ovarian cancer.

(2) Perineal Powder Use and Risk of Ovarian Cancer **[*67]** (The "Women's Health Initiative")

Houghton, Serena C., et al., *J Natl Cancer Inst, Oxford Journals*, (2014).

Background: Case-control studies have reported an increased risk of ovarian cancer among talc users; however, the only cohort study to date found no association except for an increase in serous invasive ovarian cancers. The purpose of this analysis was to assess perineal powder use and risk of ovarian cancer prospectively in the Women's Health Initiative Observational Study cohort.

Methods: Perineal powder use was assessed at baseline by self-report regarding application to genitals, sanitary napkins, or diaphragms and duration of use. The primary outcome was self-reported ovarian cancer centrally adjudicated by physicians.

Results: Among 61,576 postmenopausal women, followed for a mean of 12.4 years without a history of cancer or bilateral oophorectomy, 52.6%

reported ever using perineal powder. Ever use of perineal powder (hazard ratio $[HR]_{adj}$ = 1.06, 95% confidence interval [CI] = 0.87 to 1.28) was not associated with risk of ovarian cancer compared with never use. Individually, ever use of powder on the genitals (HR_{adj} = 1.12, 95% CI = 0.92 to 1.36), sanitary napkins (HR_{adj} = **[*68]** 0.95, 95% CI = 0.76 to 1.20), or diaphragms (HR_{adj} = 0.92, 95% CI = 0.68 to 1.23) was not associated with risk of ovarian cancer compared with never use, nor were there associations with increasing durations of use.

Conclusion: Based on our results, perineal powder use does not appear to influence ovarian cancer risk.

(3) Prospective Study of Talc Use and Ovarian Cancer (The "Nurses' Health Study")

Gertig, Dorota M., et al., *Journal of the National Cancer Institute*, Vol. 92, No. 3, February 2, 2000.

Background: Perineal talc use has been associated with an increased risk of ovarian cancer in a number of case-control studies; however, this association remains controversial because of limited supporting biologic evidence and the potential for recall bias or selection bias in case-control studies. In this study, we conducted a prospective analysis of perineal talc use and the risk of ovarian cancer.

Methods: The Nurses' Health Study is a prospective study of 121,700 female registered nurses in the United States who were aged 30-55 years at enrollment in 1976. Talc use was ascertained in 1982 by use of a self-administered questionnaire: alter exclusions, 78,630 women formed the cohort for analysis. **[*69]** We observed no overall association with ever talc use and epithelial ovarian cancer (multivariate RR = 1.09; 95% CI = 0.86-1.37) and no increase in risk of ovarian cancer with increasing frequency of use. ...

Conclusion: our results provide little support for any substantial association between perineal talc use and ovarian cancer risk overall; however, perineal talc use may modestly increase the risk of invasive serous ovarian cancer. ...

Discussion: To our knowledge, this is the first prospective analysis of talc use and ovarian cancer, and it addresses some of the potential limitations of previous case-control studies. Because we ascertained talc exposure prior to case diagnosis, the possibility for recall bias, which has been raised as a potential explanation for previous positive findings in case-control studies, is eliminated, and selection bias is reduced. We controlled for known or suspected ovarian cancer risk factors in the analysis, such as parity, oral contraceptive use, tubal ligation history, and body mass index, reducing the potential for uncontrolled confounding.

- The number of participants in the three large prospective population-based cohort studies on the association **[*70]** of talc-based powder and ovarian cancer conducted since 2000 total 191,090.

APPENDIX B

Case Control Studies and Meta Analyses

(1) Ovarian Cancer and Talc - A Case-Control Study

[Dr. Cramer's initial study]

Cramer, Daniel W., et al., *Cancer*, 50:372-376, July 15, 1982.

Opportunities for genital exposure to talc were assessed in 215 white females with epithelial ovarian cancers and in 215 control women from the general population matched by age, race, and residence. Ninety-two (42.8%) cases regularly used talc either as a dusting powder on the perineum or on sanitary napkins compared with 61 (28.4%) controls. Adjusted for parity and menopausal status, this difference yielded a relative risk of 1.92 ($P < 0.003$) for ovarian cancer associated with these practices. Women who had regularly engaged in both practices had an adjusted relative risk of 3.28 ($P < 0.001$) compared to women with neither

exposure. This provides some support for all association between talc and ovarian cancer hypothesized because of the similarity of ovarian cancer to mesotheliomas and the chemical relation of talc to asbestos, a known cause of mesotheliomas. ... No significant differences were noted between cases and controls **[*71]** in these exposures, although the intensity of talc exposure from these sources was likely affected by variables not assessed in this study.

...

(2) Perineal Exposure to Talc and Ovarian Cancer Risk

Harlow, Bernard L., et al., *Obstetrics and Gynecology*, 80:19-26, 1992.

Objective: We sought to determine whether the use of talc in genital hygiene increases the risk for epithelial ovarian cancer.

Methods: We interviewed 235 white women diagnosed with epithelial ovarian cancer between 1984-1987 at ten Boston metropolitan area hospitals and 239 population-based controls of similar race, age, and residence.

Results: Overall, 49% of cases and 39% of controls reported exposure to talc, via direct application to the perineum or to undergarments, sanitary napkins, or diaphragms, which yielded a 1.5 odds ratio (OR) for ovarian cancer (95% confidence interval [CI] 1.0-2.1). Among women with perineal exposure to talc, the risk was significantly elevated in the subgroups of women who applied it: 1) directly as a body powder (OR 1.7, 95% CI 1.1-2.7), 2) on a daily basis (OR 1.6, 95% CI 1.0-2.7). The greatest ovarian cancer risk associated with perineal talc use was observed in the subgroup of women estimated **[*72]** to have made more than 10,000 applications during years when they were ovulating and had an intact genital tract (OR 2.8, 95% CI 1.4-5.4); however, this exposure was found in only 14% of the women with ovarian cancer.

Conclusions: These data support the concept that a life-time patters of perineal talc use may increase the risk for epithelial ovarian cancer but is unlikely to be the etiology for the majority of epithelial ovarian cancers.

(3) Perineal Powder Exposure and the Risk of Ovarian Cancer

Cook, Linda S., et al., *American Journal of Epidemiology* 145:459-65, 1997.

This case-control study evaluated the risk of epithelial ovarian cancer associated with genital exposure to various forms of powder application. Cases included all women aged 20-79 years in three counties of western Washington who were diagnosed with borderline or invasive ovarian cancer from 1986 through 1988; 64.3% of eligible cases were interviewed. A sample of similarly aged women who lived in these counties, identified by random digit dialing, served as controls. ...

The "cases" totaled 329 women; the cohorts totaled 422 women. Relative risk calculated at "1.5."

(4) Genital Talc Exposure and Risk of Ovarian Cancer

Cramer, **[*73]** Daniel W., et al., *Int. J. Cancer*, 81:351-356, May 5, 1999.

Epidemiologic studies have suggested an increased risk for ovarian cancer associated with the use of talcum powder in genital hygiene, but the biologic credibility of the association has been questioned. ... Cases were more likely than controls (45% vs. 36^) to have used talc as a body powder in some manner, and the excess was confined to patients who used talc on the perineum directly or as a dusting powder to underwear or sanitary napkins. Exposure prior to rather than after the first livebirth appeared to be more harmful, and the association was most apparent for women with invasive serous cancers and least apparent for those with mucinous tumors. We conclude that there is a significant association between the use of talc in genital hygiene and risk of epithelial ovarian cancer that, when viewed in perspective of published data on

this association, warrants more formal public health warnings.

... The "cases" totaled 563 women; the cohorts totaled 523 women.

We have also proposed that talc use during periods of ovulations may carry greater risk, based on the hypothesis that ovarian surface epithelial disruption and repair accompanying **[*74]** ovulation might allow talc to become entrapped within the inclusion cysts that form with ovulation. [NOTE: This statement at page 355 is Dr. Cramer's postulation of a hypothesis. He neither re-stated nor explained this hypothesis at the *Kemp* Hearing.]

The adjusted odds ratios ranged from 0.31 to 2.21.

(5) Perineal Talc Exposure and Subsequent Epithelial Ovarian Cancer: A Case-Control Study

Wong, Cheung, et al., *Obstetrics & Gynecology*, 93:372-6, 1999.

Objective: To evaluate the role of talcum powder use as a risk factor for the development of epithelial ovarian cancer.

Methods: In a case-control study, 499 patients with epithelial ovarian cancer were frequency matched for age at diagnosis (± 5 years) with a control population of 755 patients. The odds ratio (OR) for the development of epithelial ovarian cancer was estimated using logistic regression analysis with adjustment for age at diagnosis, parity, oral contraceptive use, smoking history, family history of epithelial ovarian cancer, age at menarche, menopausal status, income, education, geographic location, history of tubal ligation, and previous hysterectomy.

Results: Two hundred twenty-one of 462 patients (47.8%) in the study population **[*75]** and 311 of 693 patients (44.9%) in the control population had ever used talcum powder (OR 0.92; 95% confidence interval [CI] 0.24, 3.62). A significant association between duration of talc use and development of epithelial ovarian cancer was not demonstrable for 1-9 years (OR 0.9; 95% CI 0.6, 1.5), for 10-19 years (OR 1.4; 95% CI 0.9, 2.2) or for more than 20 years (OR 0.9; 95% CI 0.6, 1.2). To eliminate the possible confounding variable of surgery for the management of ovarian cancer, we omitted 135 patients in the study population who underwent hysterectomy within 5 years of the diagnosis of ovarian cancer. Within this subgroup of patients, tubal ligation or hysterectomy among talc users still failed to demonstrate an increased risk for the development of ovarian cancer (OR 0.9; 95% CI 0.4, 2.2).

Conclusion: A significant association between the use of talcum powder and the risk of developing epithelial ovarian cancer is not demonstrable, even with prolonged exposure.

Discussion

The current study fails to demonstrate an association between the use of perineal talcum powder and a significant increase in the risk of epithelial ovarian cancer. These findings are at variance with a meta-analytic **[*76]** report by Gross and Berg, which demonstrated a modest increase in the risk of epithelial ovarian cancer among patients who had ever used talc. In an analysis of ten epidemiologic studies, Gross and Berg calculated an adjusted OR of 1.29 (95% CI 1.02, 1.63).

(6) Genital Powder Exposure and the Risk of Epithelial Ovarian Cancer

Rosenblatt, Karin A., et al., *Cancer Causes Control*, 22:737-742, May 5, 2011.

Abstract

Background: We conducted a population-based, case-control study to examine the association between the use of genital powder and ovarian cancer risk, including measures of extent and timing of exposure. We also assessed the relationship of powder use with risk of disease subtypes according to histology and degree of malignancy.

Methods: Information was collected during in-person interviews with 812 women and epithelial ovarian cancer diagnosed in western Washington State from 2002 to 2005 and 1,313 controls. Logistic regression was used to calculate odds ratios (ORs) and 95% confidence intervals (Cis).

Results: Overall, the perineal use of powder after bathing was associated with a slightly increased ovarian cancer risk (OR = 1.27, 95% CI: 0.97-1.66), which was most evident among **[*77]** women with borderline tumors (OR = 1.55, 95% CI: 1.02-2.37). We noted no clear pattern of risk increase on the basis of the extent of use, assessed as years in which powder was used, or as lifetime number of applications for invasive or borderline tumors, or their histologic subtypes. ...

Conclusions: The International Agency for Research on Cancer has designated perineal exposure to talc (via the application of genital powders) as a possible carcinogen in women. A modest association of ovarian cancer with this exposure was seen in our study and in some previous ones, but that association generally has not been consistent within or among studies. Therefore, no stronger adjective than "possible" appears warranted at this time.

(7) The Association Between Talc Use and Ovarian Cancer - A Retrospective Case-Control Study in Two US States

Cramer, Daniel W., *Epidemiology*, 27:334-346, May, 2016.

Background: Multiple studies of ovarian cancer and genital talc use have led only to consensus about possible carcinogenicity. Seeking greater clarity, we examined this association in 2,041 cases with epithelial ovarian cancer and 2,100 age-and — residence-matched controls.

...

Results: Overall, genital **[*78]** talc use was associated with an OR (95% CI) of 1.33 (1.16, 1.52) with a trend for increasing risk by talc-years. Women who used talc were more likely to be older, heavier, asthma sufferers, and regular analgesic users — none of which was a confounder. Dose-responses were more apparent for premenopausal women, especially nonsmokers and those heavier or postmenopausal users of menopausal hormones (hormone therapy [HT]). ...

Conclusion: Risks for epithelial ovarian cancer from genital talc use vary by histologic subtype, menopausal status at diagnosis, HT use, weight, and smoking. These observations suggest that estrogen and/or prolactin may play a role via macrophage activity and inflammatory response to talc.

(8) Perineal Talc Use and Ovarian Cancer Risk: A Case Study of Scientific Standards in Environmental Epidemiology [Meta Analysis]

Huncharek, Michael, et al., *European Journal of Cancer Prevention*, 20:501-507, November 6, 2011.

A number of observational studies (largely case-control) conducted over the last two decades suggest an association between use of talc powders on the female perineum and increased risk of ovarian cancer. A subset of these reports shows a roughly 30-60% increased **[*79]** risk of ovarian cancer associated with perineal talc exposure. A number of researchers partly base their conclusions of an association on the ...chemical relationship between talc and asbestos', the latter substance being a known human carcinogen. ...

Summary

These conclusions are based on a number of statistical, methodological, and biological issues. First, contrary to the assertions of Epstein (2008), findings from the cited studies are not consistent from study to study, and also differ by study design. Two meta-analyses by Huncharek, et al. (2003) and Langseth, et al. (2008)both show significant differences in summary ORs between population-based and hospital-based case-control studies, with the latter showing generally null

results. The Nurses' Health Study, the one prospective study that examined this association, found no risk with talc dusting. Formal statistical tests for heterogeneity in both analyses support this finding. This fact suggests the existence of bias, and standard approaches to meta-analysis indicate that the pooled OR, or in this case an OR of 1.30, is not valid in the presence of heterogeneity. Huncharek and Muscat (2007) suggest multiple possible sources of **[*80]** bias that could produce a spurious positive finding, including unaccounted for effects of cancer treatment and confounding by smoking.

...

There is no coherent biological explanation as to how talc could induce cancer of the ovary. The theories put forth to explain the statistical association between talc and ovarian cancer have changed over time with little underlying consistency. The long-standing claim that talc is chemically 'similar' to asbestos and is therefore a carcinogen is a misunderstanding of the chemical and physical properties of talc.

(9) Perineal Use of Talc and Risk of Ovarian Cancer [Meta Analysis]

Langseth, H., et al., *The Cancer Registry of Norway*, October 15, 2007.

Abstract

Ovarian cancer is one of the most common gynaecological neoplasms, especially in industrialised countries. The aetiology of the disease is not well understood, except that inherited mutations in the breast cancer genes BRCA-1 and BRCA-2 account for up to 10% of all cases, and child-bearing, oral contraceptive use and breast-feeding reduce the risk. Some environmental exposures, notably talc and asbestos, have been suspected as ovarian carcinogens.

...

The association between talc use in the perineal **[*81]** region and ovarian cancer was investigated in one cohort study, and 20 cases-control studies. In the cohort study, arguably the strongest study because of its partly prospective ascertainment of exposure, there was no association between cosmetic talc use and risk of all subtypes of ovarian cancer combined.

...

To summarise the evidence in favour of an association, a very large number of studies have found that women who used talc experienced excess risks of ovarian cancer; some results were statistically significant and some were not. There was some indication in the cohort study of an increase in serous tumours. The evidence of talc migrating to the ovaries lends credibility to such possible association. The main epidemiological evidence against the association is the absence of clear exposure-response associations in most studies, as well as the absence of an overall excess risk in the cohort study.

...

The current body of experimental and epidemiological evidence is insufficient to establish a causal association between perineal use of talc and ovarian cancer risk. Experimental research is needed to better characterize deposition, retention and clearance of talc to evaluate the ovarian **[*82]** carcinogenicity of talc.

(10) Genital Powder Use and Risk of Ovarian Cancer: A Pooled Analysis of 8,525 Cases and 9.859 Controls

Terry, Kathryn L., et al., *Cancer Prev Res (Phila)*, 6(8):811-821, August, 2013.

Abstract

Genital powder use has been associated with risk of epithelial ovarian cancer in some, but not all, epidemiologic investigations, possibly reflecting the carcinogenic effects of talc parades found in most of these products. Whether risk increases with

number of genital-powder applications and for all histologic types of ovarian cancer also remains uncertain. Therefore, we estimated the association between self-reported genital powder use and epithelial ovarian cancer risk in eight population-based case-control studies. Individual data from each study was collected and harmonized. Lifetime number of genital-powder applications was estimated from duration and frequency of use. Pooled odds ratios were calculated using conditional logistic regression matched on study and age and adjusted for potential confounders. Subtype-specific risks were estimated according to tumor behavior and histology. 8,525 cases and 9,859 controls were included in the analyses. Genital powder use was **[*83]** associated with a modest increased risk of epithelial ovarian cancer (odds ratio 1.24, 95% confidence interval 1.15-1.33) relative to women who never used powder. Risk was elevated for invasive serous (1.2, 1.09-1.32), endometrioid (1.22, 1.04-1.43), and clear cell (1.24, 1.01-1.52) tumors, and for borderline serous tumors (1.46, 1.24-1.72). Among genital powder users, we observed no significant trend (p=0,17) in risk with increasing number of lifetime applications (assessed in quartiles). We noted no increase in risk among women who only reported non-genital powder use. In summary, genital powder use is a modifiable exposure associated with small-to-moderate increases in risk of most histologic subtypes of epithelial ovarian cancer.

...

This pooled analyses of eight case-control studies suggests that genital powder use is associated with a modest 20-30% increase in risk of developing epithelial ovarian cancer, including serous, endometrioid, and clear cell tumors, but is less relevant to invasive mucinous tumors. Our findings are consistent with and extend the findings of three meta-analyses that have reported an increased risk of epithelial ovarian cancer with genital-powder use by **[*84]** including dose response and histology specific analyses.

...

NOTE: The two meta-analyses performed by Langseth and Terry work with the same 8 studies in performing their analyses. Langseth arrived at an overall Odds Ratio of 1.35 and Terry arrived at an Odds Ratio of 1.24. The participating cases and controls examined totaled 18,384.

APPENDIX C

Biologic Basis/Inflammation Studies

These studies which were cited by Dr. Graham Colditz his report in support of his statement of "Biologic Plausibility." (The "link" to each article permits the reader to assess whether the same supports Dr. Colditz's conclusions).

(1) Possible Role of Ovarian Epithelial Inflammation in Ovarian Cancer

Ness, Roberta B., et al., *Journal of the National Cancer Institute*, 91: 1459-1467, September 1, 1999.
[*http://www.ncbi.nlm.nih.gov/pubmed/10469746*]

Summary

Neither incessant ovulation nor gonadotropin stimulation of ovarian estrogen provides a completely satisfactory explanation for the genesis of ovarian cancer. We have reviewed the data suggesting that an additional mechanism that may underlie ovarian cancer is inflammation, with concomitant rapid DNA turnover and effective repair, oxidative stress, and elevation of bioactive substances. Incessant ovulation, **[*85]** a process that has been linked to ovarian cancer risk, is associated with inflammation at the level of both the epithelium and the follicle. Other factors that cause local pelvic inflammation may also increase risk. Finally, tubal ligation and hysterectomy, which diminish the potential that ovarian epithelium will be exposed to initiators of inflammation, reduce risk. Further observational and experimental data will be needed to confirm the hypothesis that inflammation is a central biologic process in ovarian cancer risk.

(2) Aspirin and Non-Steroidal Anti-Inflammatory Drags for Cancer Prevention: An International Consensus Statement

Cuzik, Jack., et al., *Lancet Oncol*, 10:501-507, May, 2009.

[*http://wwvv.ncbi.nlm.nih.gov/pubmed/19410194*]

The panel planned to produce a consensus statement on the use of aspirin and other NSAIDs for cancer prevention; however, it became clear that gaps in our understanding of appropriate dose, duration, and age of use, would not support a formal risk-benefit analysis. A specific benefit of aspirin over other NSAIDs is a lowered risk of occlusive cardiovascular events. ...

Because of uncertainties about the minimum dose and duration of aspirin treatment needed to decrease cancer incidence, and the mixed **[*86]** beneficial and adverse effects on the cardiovascular and other organ systems, the panel concluded that further clinical studies were needed to assess the risk-benefit provide of NSAIDs. ...

Conclusion

Only treatment with aspirin combines the benefit of protection against cardiovascular disease with the potential to reduce the risk of some types of cancer. Aspirin might eventually be useful for the primary prevention of some cancers in patients who already qualify for prophylactic antiplatelet therapy on the basis of cardiovascular criteria.

(3) Aspirin, Nonaspirin Nonsteroidal Anti-Inflammatory Drug, and Acetaminophen Use and Risk of Invasive Epithelial Ovarian Cancer: A Pooled Analysis in the Ovarian Cancer Association Consortium

Trabert, Britton, et al., *J Natl Cancer Inst*, 106(2): djt431, February 5, 2014.

[*http://jnci.oxfordjournals.org/content/106/2/djt431.abstract*]

Multiple lines of evidence suggest that ovarian cancer may be related to chronic inflammation. In addition to inflammatory factors associated with increased ovarian cancer risk.

Recently, intervention trials have shown that regular aspirin use is associated with reduced risk of several malignancies. However, these trials were not powered for rare cancer endpoints, and none of the **[*87]** clinical trials to date have evaluated ovarian cancer separately. ...

Our study provides estimates on the effect of aspirin on ovarian cancer risk that should be considered in risk-benefit analyses for preventive aspirin use. However, detailed questions about frequency, dose, and duration will need to be evaluated in future studies including pooled data from cohort studies. ...

In summary, this pooled analysis supports the hypothesis that regular aspirin use reduces ovarian cancer risk. Specifically, we report a statistically significant decreased risk of ovarian cancer with daily use of aspirin. Further biological and pharmacological research is necessary to understand the mechanisms of ovarian cancer risk reduction by aspirin use.

(4) Pre-Diagnostic Serum Levels of Inflammation Markers and Risk of Ovarian Cancer in the Prostate, Lung, Colorectal and Ovarian Cancer (PLCO) Screening Trial

Trabert, Britton, et al., *Gynecologic Oncology* 135:297-304, November 2, 2014.

[*http://www.ncbi.nlm.nih.gov/pubmed/25158036*]

Abstract

Objective: Pro-inflammatory mechanisms may explain the increased ovarian cancer risk linked to more lifetime ovulations, endometriosis, and exposure to talc and asbestos, as well as decreased risk with non-steroidal **[*88]** anti-inflammatory drugs. Limited data are available to estimate ovarian cancer risk associated with levels of circulating inflammatory markers.

Methods: We conducted a nested case-control study within the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial. Pre-diagnostic serum levels of 46 inflammation-related biomarkers (11 with a priori hypotheses; 35 agnostic) were measured in 149 incident ovarian cancer cases and 149 matched controls. Odds ratios (ORs) and 95% confidence intervals (Cis) were calculated using conditional logistic regression and adjusted for identified covariates.

Conclusion: These results suggest that CRP, IL-l*a*, 1L-8, and TNF-*a* are associated with increased risk of subsequently developing ovarian cancer.

Introduction

Epidemiologic evidence implicates chronic inflammation as a central mechanism in the pathogenesis of ovarian cancer, the most lethal gynecologic cancer among women in the United States. Chronic inflammation can induce rapid cell division, increasing the possibility for replication error, ineffective DNA repair and subsequent mutation. Ovarian cancer has been linked to several events and conditions which are related to inflammation and repair, **[*89]** including incessant ovulation, endometriosis, exposure to talc and asbestos, and in some studies pelvic inflammatory disease. ... Understanding the role of inflammation in ovarian cancer etiology is complicated by growing recognition that there are at least two main types of these tumors, which differ clinically and biologically. Increasing evidence suggests that some high-grade serous carcinomas, the most common and lethal subtype, arise from the fimbria of the fallopian tube rather than the ovarian surface epithelium. ...

To gain a better understanding of the etiologic role of inflammation markers in ovarian cancer development, we conducted a nested case-control study within the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. We used multiplelxed inflammatory maker panels to measure 46 inflammation-related markers, including several inflammation markers with existing evidence of associations with ovarian function or ovarian cancer risk.

NOTE: None of the peer-reviewed articles cited by Dr. Colditz in his expert report of July 31, 2015 discusses talcum powder, talc's relationship to ovarian cancer, nor a hypothesis of how talc triggers a biologic mechanism resulting **[*90]** in ovarian cancer.

APPENDIX D

Studies Concluding That Talc is Not a Carcinogen, as per the Testimony of Dr. Lewis Chodosh

(1) Talc Induces Apoptosis in Human Malignant Mesothelioma Cells *In Vitro*

Nasreen, Najmunnisa, et al., *Am J Respir Crit Car Med*, 161:595-600, February, 2000.

Pleurodesis with talc is an accepted method for the treatment of symptomatic pleural effusions secondary to mesotheliomas. Patients with mesothelioma who have talc-induced pleurodesis have a lower morbidity than do those who do not have pleurodesis. The mechanisms whereby talc mediated these effects were considered to be secondary to a decrease or absence of a pleural effusion. The possibility that talc may directly affect malignant cells was not considered. The present study was designed to evaluate if talc directly effects cell death of malignant mesothelioma cells (MMC) or normal pleural mesothelial cells (PMC). ... The present study has demonstrated that talc induces apoptosis in MMC without affecting normal mesothelial cells of the pleura.

(2) Selective Apoptosis of Lung Cancer Cells with Talc

Lee, P., et al., *European Respiratory Journal*, 35:450-452.

... A number of studies have demonstrated superior efficacy **[*91]** of talc over other sclerosing agents commonly used for the palliation of malignant pleural effusions, and talc is the preferred

pleurodesis agent according to a survey of chest physicians. Despite talc's wide clinical use, the exact mechanisms for its efficacy as well as its apoptotic effects on lung cancer in vitro have not been studied. The objectives of our study were to determine if talc caused apoptosis of lung cancer cells, and to compare talc against other commonly administered intrapleural sclerosing agents by extending the experiments to include bleomycin and doxycline.

Our preliminary the use of talc for malignant effusion as it selectively causes apoptosis of lung cancer cells, and spares normal mesothelium pivotal for inciting inflammatory process necessary for pleural fibrosis. Studies are underway to compare the in vitro results with In vivo response, as well as to assess the impact on patient survival.

(3) Talc Mediates Angiostasis in Malignant Pleural Effusions *via* Endostatin Induction

Najmunnisa, N., et al., *Eur Respir J*, 29:761-769, 2007.

Abstract

Talc remains the most effective sclerosing agent for pleurodesis. However, its mechanism of action in resolving pleural malignant **[*92]** disease remains unclear.

The present study evaluated the angiogenic balance in the pleural space in patients with malignant pleural effusions (MPE) following talc insufflation. ...

In conclusion, talc alters the angiogenic balance in the pleural space from a biologically active and angiogenic environment to an angiostatis milieu. Functional improvement following talc poudrage in patients with malignant pleural effusions may, in part, reflect these alterations in the pleural space.

(4) *In Vitro* Response of Rat Pleural Mesothelial Cells to Talc Samples in Genotoxicity Assays (Sister Chromatid Exchanges and DNA Repair)

Endo-Capron, S., et al., *Toxic. In Vitro*, 7:714, January, 1993.

Abstract

The genotoxicity of three samples of talc has been determined using in vitro cell systems previously developed for testing asbestos fibres. The talc samples used consisted of particles of respirable size in order to test the effect of particles likely to be deposited in the lung. Genotoxicity was tested in cultures of rat pleural mesothelial cells (RPMC) using genotoxicity assays for unscheduled DNA synthesis (UDS) and sister chromatid exchanges (SCEs). The effects were compared with those obtained with **[*93]** negative controls (attapulgite and anatase) and positive controls (chrysotile and crocidolite asbestos). In contrast to asbestos, none of the talc samples, nor the negative controls, and induced enhancement of (JDS or SCEs in treated cultures in comparison with the untreated cultures.

[NOTE: As testified to by Dr. Chodosh, these rodents were exposed for their entire lifetime to living in "clouds of talc for hours a day Testimony of 8/19/16, P104, L23 thru P106, L8].

(5) Pycnogenol® Reduces Talc-Induced Neoplastic Transformation in Human Ovarian Cell Cultures

Buzzard, Amber R., et al., *Phytother. Res.*, 2:579-586 (2007).

Talc and poor diet have been suggested to increase the risk of developing ovarian cancer; which can be reduced by a diet rich in fruit and vegetables. Talc is ubiquitous despite concern about its safety, role as a possible carcinogen and known ability to cause irritation and inflammation. It was recently shown that Pycnogenol® (Pyc; a proprietary mixture of water-soluble bioflavonoids extracted from French maritime pine bark) was selectively toxic to established malignant ovarian germ cells. This study investigated talc-induced carcinogenesis and Pyc-induced chemoprevention. Normal human **[*94]** epithelial and granulosa ovarian cell lines and polymorphonuclear neutrophils (PMN) were treated with talc, or pretreated with Pyc then talc. Cell viability, reactive oxygen species (ROS)

generation and neoplastic transformation by soft agar assay were measured. Talc increased proliferation, induced neoplastic transformation and increased ROS generation time-dependently in the ovarian cells and dose-dependently in the PMN. Pretreatment with Pyc inhibited the talc-induced increase in proliferation, decreased the number of transformed colonies and decreased the ORS generation in the ovarian cells. The data suggest that talc may contribute to ovarian neoplastic transformation and Pyc reduced the talc-induced transformation. Taken together, Pyc may prove to be a potent chemopreventative agent against ovarian carcinogenesis. ...

Effect of Talc on ROS Generation in Normal Ovarian Cells

Talc caused an initial dose-dependent decrease in ROS generation (24 h) which increased with time in OSE2a cells. However, as time increased, ROS generation rebounded and increased compared with the values at 24 h.

(6) Utilization of Gene Profiling and Proteomics to Determine Mineral Pathogenicity in a Human **[*95]** Mesothelial Cell Line (LP9/TERT-1)

Hillegass, Jedd M., et al., *Journal of Toxicology and Environmental Health, Part A*, 73:423-436, 2010.

Identifying and understanding the early molecular events that underscore mineral pathogenicity using *in vitro* screening tests is imperative, especially given the large number of synthetic and natural fibers and particles being introduced into the environment. ... To verify that LP9/TERT-1 cells were more sensitive than other cell types to asbestos, human ovarian epithelial cells (IOSE) were also utilized in microarray studies. Upon assessing changes in gene expression via microarrays, principal component analysis (PCA) of these data was used to identify patterns of differential gene expression. PCA of microarray data confirmed that LP9/TERT-1 cells were more responsive than IOSE cells to crocidolite asbestos or nonfibrous talc, and that crocidolite asbestos elicited greater responses in both cell types when compared to nonfibrous talc, $Ti0_2$, or glass beads. ...

(7) Long Term Sequelae After Talc Pleurodesis for Spontaneous Pneumothorax

Viskum, K., et al., *Pneumologic*, 43:105-106, 1989.

Talc is a hydrated magnesiumsilicate ($Mg_3,Si_2O_{10}(OH)_2$) which was found **[*96]** widespread industrial and medical use, i. ex. Powder for surgical gloves, wound powder and it has been used to provoke pleurodesis for more than 50 years. The main indications for the latter use or recurrent effusion due to malignancy and recurrent pneumothorax.

Due to the harmful action of asbestos, which too is a magnesiumsilicate, there has been some anxiety, that similar effects could be provoked by talc. So far we have no confirmation of this suspicion. One reason could be that talc is not harmful, another that the observation time after pleurodesis was too short We also have to observe, that talc in some cases has been contaminated with asbestos. ...

Conclusion

Talc pleurodesis for spontaneous pneumothorax seems not within the present observation time to carry any risk for the development of mesothelioma. Only moderate changes were observed in the pleura and no serious damage has occurred in ventilatory function, as judged from spirometry. Talc pleurodesis is highly effective in preventing relapses of pneumothorax also on long term basis.

(8) Long-Term Follow-Up of Thoracoscopic Talc Pleurodesis for Primary Spontaneous Pneumothorax

Gyorik, S., et al., *Eur Respir J*, 29:757-760, April **[*97]** 4, 2007.

Abstract

The aim of the present study was to evaluate the

long-term outcome of patients with primary spontaneous pneumothorax treated with talc pleurodesis.

A follow-up study was undertaken in all patients with primary spontaneous pneumothorax who underwent talc pleurodesis for prolonged air leak or recurrence using thoracoscopy.

In total, 112 patients underwent pleurodesis and follow-up data was obtained in 63 (56% patients: 45 patients were available for clinical follow-up, 14 for telephone follow-up and four were dead. The causes of death were unrelated to the pleurodesis. There were no episodes of acute respiratory failure following pleurodesis. A total of 56 (95%) out of the cohort of 59 patients had a successful pleurodesis. Surgical pleurectomy was required in three (5%) patients for persistent air leak. Median duration of follow-up after talc pleurodesis was 118 months. Long-term success was observed in 53 (95%) out of 56 patients. Recurrent pneumothorax was observed in three (5%) out of 56 patients. Patients with successful talc pleurodesis had a median forced vital capacity (FVC) of 102% and median total lung capacity of 99% at follow-up. Comparing smokers and nonsmokers, **[*98]** the forced expiratory volume in one second (FEV_1) was significantly lower in smokers and there was a tendency for FEV_1 /FVC ratio to be lower in smokers.

Talc pleurodesis in patients with primary spontaneous pneumothorax via thoracoscopy is an effective procedure associated with normal lung function in patients who do not smoke.

(9) Is Talc Pleurodesis Safe for Young Patients Following Primary Spontaneous Pneumothorax?

Hunt, Ian, et al., *Interactive Cardio Vascular and Thoracic Surgery*, 6:117-120, 2007.

Summary

A best evidence topic in cardiothoracic surgery was written according to a structured protocol. The question addressed was whether talc used for pleurodesis in young patients with a spontaneous pneumothorax has any long-term adverse effects. One hundred and eighty-one papers were identified using the search below. Eight papers presented the best evidence to answer the clinical question. The author, journal, date and country of publication, patient group studies, study type, relevant outcomes, results, and study weaknesses of the papers are tabulated. We conclude that talc pleurodesis in young patients with a spontaneous pneumothorax appears to have minimal long-term adverse consequences. **[*99]**

APPENDIX E

Statements of Agencies Which Study Cancer

(1) National Cancer Institute

The NCI website was discussed repeatedly throughout the *Kemp* Hearing. Both sides acknowledge it to be an informative locus. The link below will take the reader to the NCI's most recent formal statement on talc and ovarian cancer; it is dated March 8, 2016 and is entitled, Talc and ovarian cancer: what the most recent evidence shows.

[*http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.2437*]

Ovarian cancer is rare. The incidence rate for ovarian cancer between 2006 and 2010 was 12.5 cases per 100,000 women. Women with a family history of ovarian cancer are at increased risk, and those with an inherited predisposition to ovarian cancer, such as a BRCA1 or BRCA2 mutation, have a very high risk of developing ovarian cancer (refer to the PDQ summary on *Genetics of Breast and Gynecologic Cancers* for more information). Other risk factors for ovarian cancer include obesity, nulliparity, and use of postmenopausal hormone therapy. Factors associated with a decreased risk of ovarian cancer include use of oral contraceptives, multiple pregnancies, breast-feeding, and tubal ligation.

The evidence is inadequate to determine whether

perineal talc exposure is associated with an **[*100]** increased risk of ovarian cancer. Results from case-control and cohort studies are inconsistent. A meta-analysis of 16 studies observed an increased risk with the use of talc (RR, 1.33; 95% CI, 1.16-1.45); however, there was no evidence of a dose response. A pooled analysis from the Ovarian Cancer Association Consortium, composed of multiple case-control studies, included 8,525 cases and 9,859 controls. A modest increased risk of epithelial ovarian cancer associated with genital powder use (OR, 1.24; 95% CI, 1.15-1.33) was observed but the trend across increasing lifetime number of applications was not statistically significant (*P* trend = .17). Updated: February 4, 2016; Accessed: August 4, 2016. ...

(2) U.S. Food and Drug Administration. FDA Website accessed August 4, 2016

Protecting and Promoting *Your* Health.

Published scientific literature going back to the 1960s has suggested a possible association between the use of powders containing talc and the incidence of ovarian cancer. However, these studies have not conclusively demonstrated such a link, or if such a link existed, what risk factors might be involved. Nevertheless, questions about the potential contamination of talc with asbestos **[*101]** have been raised since the 19702.

See also the court's discussion of the FDA letter of 4/1/14 and of the *CFR 740.1* (both at Section VII of this Opinion).

FDA Website accessed September 1, 2016.

[*Code of Federal Regulations, Title 21*, Volume 3, Revised as of April 1, 2015]

[CITE: *21CFR182.2437*]

TITLE 21--FOOD AND DRUGS CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION (CONTINUED)

PART 182 -- SUBSTANCES GENERALLY RECOGNIZED AS SAFE

Subpart C--Anticaking Agents

Sec. 182.2437 Magnesium silicate.

(a) Product. Magnesium silicate.

(b) Tolerance. 2 percent.

(c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in table salt in accordance with good manufacturing practice.

[*http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.2437*]

(3) American Cancer Society

It has been suggested that talcum powder might cause cancer in the ovaries if the powder particles (applied to the genital area or on sanitary napkins, diaphragms, or condoms) were to travel through the vagina, uterus, and fallopian tubes to the ovary.

Many studies in women have looked at the possible link between talcum powder and cancer of the ovary. Findings have been mixed, with some studies reporting a slightly increased risk and some reporting no increase. **[*102]** Many case-control studies have found a small increase in risk. But these types of studies can be biased because they often rely on a person's memory of talc use many years earlier. Two prospective cohort studies, which would not have the same type of potential bias, have not found an increased risk.

For any individual woman, if there is an increased risk, the overall increase is likely to very be small. Still, talc is widely used in many products, so it is important to determine if the increased risk is real. Research in this area continues.

[*http://www.cancer.org/cancer/cancercauses/other*

carcinogens/athome/talcum-powder-and-cancer]

(4) World Health Organization, International Agency Research on Cancer (p. 412-413).

6.1 Cancer in humans

There is *inadequate evidence* in humans for the carcinogenicity of inhaled talc not containing asbestos or asbestiform fibres.

There is *limited evidence* in humans for the carcinogenicity of perineal use of talc-based body powder.

6.2 Cancer in experimental animals

There is *limited evidence* in experimental animals for the carcinogenicity of talc not containing asbestos or asbestiform fibres.

6.3 Overall evaluation

Perineal use of talc-based body powder *is possibly carcinogenic to humans (Group 2B)*.

6.4 Rationale

In making this evaluation the Working **[*103]** Group considered the human and animal evidence as well as evidence regarding the potential mechanisms through which talc might cause cancer in humans. ... For perineal use of talc-based body powder, many case-control studies of ovarian cancer found a modest, but unusually consistent, excess in risk, although the impact of bias and potential confounding could not be ruled out. In addition, the evidence regarding exposure-response was inconsistent and the one cohort study did not provide support for an association between talc use and ovarian cancer. Concern was also expressed that exposure was defined in a variety of ways and that some substances called talc may have contained quartz and other potentially carcinogenic materials. A small number of Working Group members considered the evidence to be inadequate. Despite these reservations, the Working Group concluded that the epidemiological studies taken together provide *limited evidence* of an association between perineal use of talc-based body powder and an increased risk for ovarian cancer.

[NOTE: All italicized words in original text]

(5) The American College of Obstetricians and Gynecologists, Frequently Asked Questions FAQ096, Gynecologic **[*104]** Problems

What is cancer of the ovary?

Cancer of the ovary is a disease that affects [effects] one or both *ovaries*.

What are the risk factors for epithelial ovarian cancer?

Certain risk factors are associated with epithelial ovarian cancer. The following factors have been shown to increase a woman's risk of getting cancer of the ovary:

• Age older than 55 years.

• Family history of breast cancer, ovarian cancer, colon cancer, or endometrial cancer (cancer of the lining of the *uterus*)

• Personal history of breast cancer

• Certain changes (*mutations*) in *BRCA1* or *BRCA2*

• Never having had children

• Infertility

• *Endometriosis*

[NOTE: All bold words in original text]

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